

The opinion in support of the decision being entered today is not binding precedent of the Board.

Paper ~~48~~ 28

Filed by: Trial Section Motions Panel  
Box Interference  
Washington, D.C. 20231  
Tel: 703-308-9797  
Fax: 703-305-0942

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

**MAILED**

**JUN 11 2002**

BOARD OF REGENTS OF THE  
UNIVERSITY OF WASHINGTON  
(5,302,529),

Junior Party,  
v.

**ELI LILLY & CO.**  
(09/185,663),

Senior Party.

**PAT. & T.M. OFFICE  
BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Interference No. 104,733

Before SCHAFER, TORCZON, and TIERNEY, Administrative Patent Judges.

TIERNEY, Administrative Patent Judge.

**JUDGMENT**  
(PURSUANT TO 37 CFR § 1.640)

This interference is before a motions panel for a decision on preliminary motions.  
Oral argument took place on April 3, 2002. No transcript of the oral argument is available as the parties did not provide a court reporter.

I. Summary of the Decision

The issues presented in this interference are straightforward. University of Washington ("UW") has requested a judgment of no interference-in-fact. As permitted by the rules, Lilly has requested that, prior to determining the question of no interference-in-fact, we designate an additional UW claim as corresponding to the count.

The Federal Circuit has stated that no interference-in-fact means that there is no interfering subject matter. Thus, no interference-in-fact means that the parties are claiming different patentable inventions, an example of which occurs when the claimed subject matter of a party's patent would not impede the granting of an applicant's claims. As such, the issues raised by the parties are simply a question of whether or not UW's patent claims would prevent the issuance of Lilly's claims.

There is a rebuttable presumption that each claim designated as corresponding to a count defines the same patentable invention as all other claims designated as corresponding to the count. Indeed, 37 CFR § 1.601(j) states that:

An "interference-in-fact" exists when at least one claim of a party that is designated to correspond to a count and at least one claim of an opponent that is designated to correspond to the count define the same patentable invention.

Accordingly, in analyzing the question of no interference-in-fact, we compare a party's corresponding claims to an opponent's corresponding claims. Specifically, we presume that the subject matter of a party's corresponding claims are "prior art" to an opponent's corresponding claims in order to determine whether or not the parties invented the same patentable invention. Where a party's corresponding claims are separately

patentable from an opponent's corresponding claims, a judgment of no interference-in-fact is appropriate.

Presently, UW is involved in this interference on the basis of UW claim 3, a "species" claim. Lilly has requested that UW claim 1, a "genus" claim, be added to the interference as corresponding to Count 1, the sole count in the interference.

UW's corresponding "species" claim does not anticipate or render obvious any of Lilly's corresponding claims. Nor would UW's "genus" claim, should it correspond, anticipate or render obvious any of Lilly's corresponding claims. Accordingly, UW's species and genus claims are not an impediment to granting Lilly's corresponding claims. As such, we grant UW's motion for no interference-in-fact.

The parties have entered into a vigorous dispute as to the relative merits of the Board's precedential decision in *Winter v. Fujita*, 53 USPQ2d 1234 (Bd. Pat. App. & Int. 1999). As the questions presented in this interference do not require our reliance on any issue resolved in *Winter*, we need not address the parties' comments regarding that decision.

## II. The Technology in Question

Generally, the technology involved in this interference relates to cDNA that codes for a polypeptide ("protein") having human protein C activity. Protein C is a zymogen, or inactive precursor, of a plasma serine protease, activated protein C ("APC"). Specifically, protein C is formed as a single-chain polypeptide that undergoes processing to form a two-chain molecule having a heavy chain and a light chain that are

connected via disulfide bonds. This two-chain intermediate is converted to APC by cleaving a 12-residue peptide from the heavy chain. APC plays a critical role in the regulation of blood coagulation as it represents a physiological mechanism for blood anticoagulation.<sup>1</sup>

To understand the nature of cDNA it is necessary to understand the function of DNA. DNA ("deoxyribonucleic acid") is the blueprint of an organisms genetic makeup as it is the primary genetic material. In an organism, a portion of DNA, a gene, may undergo transcription to form mRNA (messenger ribonucleic acid). The mRNA in turn, may then be translated to form a polypeptide, e.g., an enzyme or a structural protein.

DNA is the term used to represent the complex macromolecules made up of nucleotide units. A nucleotide unit is characterized by a specific combination of a base, a sugar and a phosphoric acid residue. There are four different nucleotide units in DNA: adenine ("A"), guanine ("G"), cytosine ("C") and thymine ("T").

As explained in *In re Deuel*:

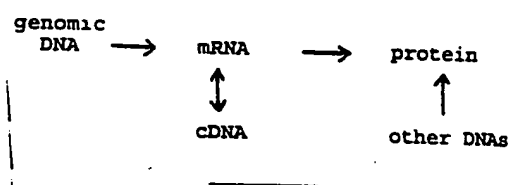
A sequential grouping of three such nucleotides (a "codon") codes for one amino acid. A DNA's sequence of codons thus determines the sequence of amino acids assembled during protein synthesis. Since there are 64 possible codons, but only 20 natural amino acids, most amino acids are coded for by more than one codon. This is referred to as the "redundancy" or "degeneracy" of the genetic code.

DNA functions as a blueprint of an organism's genetic information. It is the major component of genes, which are located on chromosomes in the cell nucleus. Only a small part of chromosomal DNA encodes functional proteins.

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<sup>1</sup>A detailed discussion of the mechanism by which protein C down regulates blood coagulation is provided in Bang et al., U.S. Patent No. 4,775,624. (Ex 1018).

Messenger ribonucleic acid ("mRNA") is a similar molecule that is made or transcribed from DNA as part of the process of protein synthesis. Complementary DNA ("cDNA") is a complementary copy ("clone") of mRNA, made in the laboratory by reverse transcription of mRNA. Like mRNA, cDNA contains only the protein-encoding regions of DNA. Thus, once a cDNA's nucleotide sequence is known, the amino acid sequence of the protein for which it codes may be predicted using the genetic code relationship between codons and amino acids. The reverse is not true, however, due to the degeneracy of the code. Many other DNAs may code for a particular protein. The functional relationships between DNA, mRNA, cDNA, and a protein may conveniently be expressed as follows:



*In re Deuel*, 51 F.3d 1552, 1554, 34 USPQ2d 1210, 1211 (Fed. Cir. 1995).

### III. Findings of Fact

#### 1. Real Parties in Interest

##### a. Junior Party

F1. University of Washington ("UW") is the owner of the entire right, title and interest in the involved U.S. Patent No. 5,302,529 ("529"). Zymogenetics, Inc. is the exclusive licensee of the '529 patent. (Paper No. 11, Notice as to Real Parties In Interest, p. 2).

b. Senior Party

F2. Eli Lilly & Co. ("Lilly") is the real party in interest in the involved U.S. Reissue Patent Application 09/185,663. (Paper No. 5, Eli Lilly & Co. Identification of Real Party in Interest, p. 2).

2. Accorded Priority Benefit

a. Junior Party

F3. UW's involved U.S. Patent No. 5,302,529 issued on April 12, 1994, based upon U.S. Application No. 07/512,961, filed April 23, 1990. Solely for the purposes of priority, UW '529 has been accorded benefit of the filing date of:

U.S. Patent No. 4,968,626, issued November 6, 1990, based upon U.S. Application 06/766,109, filed August 15, 1985.

(Notice Declaring Interference, Paper No. 1, p. 3).

b. Senior Party

F4. Lilly's involved '663 reissue application is based upon U.S. Patent No. 4,775,624, which issued on October 4, 1988 from U.S. Application 06/699,967, filed February 8, 1985. (Notice Declaring Interference, Paper No. 1, p. 3).

3. The Count and Claim Correspondence

F5. Count 1, the sole count in the interference, is claim 3 of UW's U.S. Patent No. 5,302,529.

UW '529 claim 3 reads as follows:

3. The plasmid or transfer vector of claim 1, comprising the cDNA sequence of FIG. 3, from bp 127 to bp 1383.

F6. The claims of the parties are as follows:

UW: 1-4  
Lilly: 1-82 and 84-90

The claims of the parties that have been designated as corresponding to Count 1 are:

UW: 3  
Lilly: 1-82 and 84-90

The claims of the parties that were *not* designated as corresponding to Count 1 are:

UW: 1, 2 and 4  
Lilly: None

(Notice Declaring Interference, Paper No. 1, p. 4).

4. Relevant Facts Admitted By Lilly

a. Differences between the cDNA Sequence of UW Claim 3 and Lilly's Claimed Sequences

Lilly has admitted, among other things, the following material facts presented by UW.

F7. The human protein C cDNA sequence of UW claim 3, from bp 127 to bp 1383 of Foster's Fig. 3, encodes a protein of 419 amino acids, which is a precursor of protein C.

(UW Preliminary Motion 1, Paper No. 17, p. 2, ¶4; Lilly Opposition 1, Paper No. 27, p. 2, ¶4, admitting first sentence of UW fact 4.)

F8. Comparing the sequence of UW Fig. 3, bp 127 to bp 1383, with the pertinent portions of the cDNA sequence of Lilly claim 1, two nucleotide differences are revealed in the coding region:

- 1) UW Fig. 3, nucleotide 423 (third position of codon 99) is thymine ("T"), whereas Lilly's is guanine ("G").
- 2). UW Fig. 3, nucleotide 768, (third position of codon 214) is cytosine ("C"), whereas Lilly's is thymine ("T").

(Paper No. 17, p. 3, ¶6; Paper No. 27, p. 3, admitting UW facts 6-16.) Both Lilly and UW's cDNA sequences are said to encode for human protein C. (Paper No. 27, additional facts ¶¶4, 6 and 7).

F9. The nucleotide variations between UW's Fig. 3 cDNA sequence and the sequence of Lilly claim 1 may be a DNA polymorphism. A polymorphism is defined as one of two different but normal nucleotide sequences existing at a particular site in DNA. The polymorphism may exist in the same individual, e.g., a heterozygous individual or among different individuals, and may encode the same or a different amino acid sequence. (Paper No. 17, pages 2-3, ¶7; Paper No. 27, p. 3, admitting UW facts 6-16.)

F10. According to several of Lilly's named inventors the variations between Lilly's sequence and UW's "may represent a true genetic variant." (Paper No. 17, page 4, ¶8;



Paper No. 27, p. 3, admitting UW facts 6-16.)

F11. In seeking to provoke an interference with UW's '529 patent, Lilly represented to the reissue application examiner that:

. . . it is very likely that the actual Foster [UW] sequence is identical to the corresponding Bang [Lilly] sequence. Indeed, the sequence deposited by Foster in GenBank is **identical** to the corresponding sequence in claim 1 of the Bang application.

Lilly also informed the examiner that:

*The Differences Between the Bang and Foster Sequences are Probably Foster*

*Mistakes*

As the Patent Office has recently recognized, it is well known that sequencing errors are a common problem in molecular biology. [omitted footnote] Evidence supporting the conclusion that the differences between the Bang and Foster sequences are due to sequencing errors by Foster may be found within the Foster patents themselves: the protein C DNA sequences shown in Figure 2 of Foster contains only one of the base differences: that at position 99. Further evidence may be found in the publications of Foster. Specifically, Foster published articles in the *Proceedings of the National Academy of Sciences* that showed DNA sequences matching both Patent Figure 3 (two base differences) and Figure 2 (one base difference). [omitted footnote] Later, Foster made a deposit of their protein C DNA sequence in GenBank; this deposited sequence is **identical** to the sequence of the Bang application.

\* \* \*

Applicants submit that this evidence, when viewed as a whole, clearly supports the conclusion that the two nucleotide differences in the Foster

sequence are due to sequencing errors, and not due to true differences in cDNA sequence.

(Paper No. 17, pages 6-8, ¶13, bold emphasis added; Paper No. 27, p. 3, admitting UW facts 6-16.)

F12. GenBank is a publicly accessible database of nucleic acid sequences.

According to a review article published in 1985, it was GenBank's practice during the 1980's to gather nucleic acid sequences for their database from published scientific literature. (Paper No. 17, p. 8, ¶14; Paper No. 27, p. 3, admitting UW facts 6-16.)

F13. Lilly advised the reissue application examiner that Lilly's sequence was deposited with GenBank under Accession Number X02750. Specifically, Lilly informed the examiner that there is "absolute similarity" between the sequence in Lilly's '663 reissue application and the GenBank X02750 sequence. (Paper No. 17, p. 8, ¶16; Paper No. 27, p. 3, admitting UW facts 6-16.)(Paper No. 17, p. 8, ¶16; Paper No. 27, p. 3, admitting UW facts 6-16.)

F14. Lilly informed the reissue application examiner that GenBank Sequence NM\_000312 was UW's protein C DNA sequence. (Paper No. 17, p. 9, ¶17; Paper No. 27, p. 3, fact 17, stating that Lilly had a good faith belief that its statements regarding the origins of UW's sequences were true and if Lilly was in error, the error was inadvertent.)

F15. Lilly's reissue prosecution statements that Foster deposited the NM\_0003212 are *mistaken*. The record demonstrates that the NM\_0003212 sequence was derived from Lilly's X02750 sequence. (Paper No. 17, p. 10, ¶20; Paper No. 27, p. 3, admitting UW facts 18-21).

b. Coding Sequence Unpredictability

F16. Even if one predicted the existence of at least one DNA polymorphism in a gene, one could not predict where in the coding sequence the difference(s) would occur, how many differences would occur, or what the differences would be. As such, provided with the coding sequence of a single gene, one of ordinary skill in the art could not predict with accuracy the number or location of DNA differences between the genes of different people encoding the same protein. (Paper No. 17, p. 5, ¶10; Paper No. 27, p. 3, admitting UW facts 6-16.)

F17. The two codon differences between UW's claim 3 sequence and Lilly's claim 1 sequence could not have been predicted in advance based on knowledge of either Lilly's nucleotide sequence or Lilly's amino acid sequences. (Paper No. 17, p. 5, ¶11; Paper No. 27, p. 3, admitting UW facts 6-16.)

F18. One of ordinary skill in the art could not have predicted the particular DNA sequence of UW claim 3 based on the amino acid sequence of human protein C light chain, such as that recited in Lilly claim 81, or a particular DNA encoding that amino acid sequence, such as that provided in Lilly claim 82. (Paper No. 17, p. 11, ¶21; Paper No. 27, p. 3, admitting UW facts 18-21).

IV. Opinion

An Administrative Patent Judge ("APJ") declared this interference based, in part, on statements made during the examination of Lilly's reissue application. UW claim 3 is directed to a plasmid or transfer vector comprising a string of base pairs identified in the cDNA sequence of *UW Figure 3*. During the prosecution of Lilly's reissue application, Lilly represented to the examiner that Foster ("UW") had deposited a nucleotide sequence encoding protein C that was **identical** to the corresponding sequence of Lilly's claim 1. (UW Preliminary Motion 1, Paper No. 17, pages 6-8, ¶13, Lilly Opposition 1, Paper No. 27, p. 3, admitted facts 6-16). According to Lilly:

Applicants submit that this evidence, when viewed as a whole, clearly supports a conclusion that the two nucleotide differences in the Foster sequence [*UW Figure 3*] are due to sequencing errors, and not due to true differences in cDNA sequence.

*Id.*

When the interference was declared, the Office was unaware that the purported "Foster sequence," Accession No. NM\_00312 was **Lilly's own sequence**. (Paper No. 17, p. 9, ¶¶17, 20; Paper No. 27, p. 3, Lilly stated that it had a good faith belief that its statements were true and that any error was "inadvertent."). In light of the evidence provided by UW, we find that Lilly's statements regarding the origin of the deposited sequence were incorrect and that the claimed UW species and Lilly species are apparently genetic variants. (See, Paper No. 17, p. 4, ¶8, Paper No. 27, p. 3, admitting facts 6-16).

UW has filed a preliminary motion seeking a judgment of no interference-in-fact based on the differences between the sequence of UW claim 3 and the sequences recited in Lilly's claims. (UW Preliminary Motion 1, Paper No. 17, p. 1). In response to UW's motion, Lilly filed a preliminary motion requesting that the interfering subject matter be redefined to have UW claim 1 designated as corresponding to Count 1. (Lilly Preliminary Motion 1, Paper No. 27, p. 1).<sup>2</sup>

1. What is Required for a Determination of "No Interference-In-Fact"

Both UW and Lilly agree that there is an interference-in-fact when two parties are claiming the same patentable subject matter. The parties, however, disagree as to the test for determining whether the parties claims define the same patentable subject matter.

While 35 U.S.C. § 135(a) sets forth the requirements for declaring an interference, the statute fails to explicitly state the requirements for determining whether there is no interference-in-fact once an interference has been declared. To aid us in our understanding, we look to the United States Patent & Trademark Office's ("USPTO") rules regarding no interference-in-fact. Yet, as the comments to the rules specifically state that USPTO would continue to follow the decisions rendered in Case

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<sup>2</sup> Rule 633(i) allows a party to respond to a motion for no interference in fact by filing, among other things, a motion under Rule 633(c) to redefine the interfering subject matter.

*v. CPC International, Inc.*,<sup>3</sup> *Aelony v. Arni*,<sup>4</sup> and *Nitz v. Ehrenreich*,<sup>5</sup> we review these decisions prior to our review of the USPTO rules. Notice of Final Rules, 49 Fed. Reg. 48416, 48,421 (Dec. 12, 1984).

A. The Opinions of the Federal Circuit and the Court of Customs and Patent Appeals ("CCPA")

1. *Nitz v. Ehrenreich*

*Nitz* involved an appeal from the Board of Patent Interferences<sup>6</sup> awarding priority of invention to Ehrenreich. Specifically, the Board awarded priority of invention as to two counts, counts 1 and 2, to Ehrenreich. Nitz appealed the decision arguing, among other things, that there was no interference-in-fact as to either count.

The interference was provoked when senior party Ehrenreich copied, in modified form, claims 3 and 13 of Nitz's U.S. Patent No. 3,552,533. The subject matter of the two copied claims involved carbonized articles having a modifying agent to increase the coefficient of friction of carbon. Of note, count 1 required up to about 48 percent by weight of a friction modifier and count 2 required carbonized layers of filamentary materials.

During the Board proceeding, Nitz argued that the counts did not define common

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<sup>3</sup>730 F.2d 745, 221 USPQ 196 (Fed. Cir. 1984).

<sup>4</sup>547 F.2d 566, 192 USPQ 486 (CCPA 1977).

<sup>5</sup>537 F.2d 539, 190 USPQ 413 (CCPA 1976).

<sup>6</sup>The decision in *Nitz* occurred prior to the merger of the Board of Interferences with the Board of Patent Appeals.

subject matter that was claimed by both parties. In reviewing Nitz's arguments with respect to count 1, the Board recommended to the Commissioner that the interference be dissolved. Specifically, the Board viewed Nitz's limitation of up to 12 weight percent of a friction modifier as defining a patentably distinct invention from that of count 1, which required up to about 48 weight percent of the friction modifier. The Commissioner, however, disapproved of the recommendation as the Commissioner was of the opinion that the amount of the modifier was not a critical limitation and that there was no basis for Nitz and Ehrenreich's claims to exist in separate patents. As to count 2, the Board determined that the count's failure to recite the term "woundup," as found in Nitz's claimed carbonized layers, was not a patentable distinction.

Additionally, Nitz raised the issue of Ehrenreich's "right to make count 1." As to this issue, the Board determined that Ehrenreich's disclosure was sufficient to support the limitations of the count. Having decided the issues of no interference-in-fact and right to make the counts, the Board awarded priority on both counts to Ehrenreich. Nitz appealed.

In reviewing the question of interference-in-fact and the court's jurisdiction to consider that issue, the CCPA stated:

The existence of common subject matter defined by the interference count is a prerequisite for an award of priority, i.e., the existence or nonexistence of interfering subject matter goes to the very foundation on which an interference rests. Determination of the presence or absence of interfering subject matter is "logically related" to the jurisdiction-conferring issue of priority because that determination necessarily precedes a priority award.

As to the question of no interference-in-fact, the CCPA compared the disclosure and claims of Nitz with the count and the disclosure of Ehrenreich. According to the CCPA:

In the case before us the materiality of the questioned limitation and its variation must be determined in a two-step process wherein the first inquiry is [1] whether the variation changes a material aspect of the patentee's invention (here, whether the maximum amount of friction modifier of "up to 12 percent by weight" is a material limitation) and, if that inquiry be decided in the affirmative, the second inquiry is [2] whether the variation is itself a material variation (here, whether "up to 48% by weight" results in the counts being drawn to a different invention).

*Id.* at 544, 190 USPQ at 417.

Conducting the two-step inquiry, the CCPA focused on Nitz's description that at least 80 weight percent carbon was a critical feature of the invention and the limitation that the modifier was present in an amount "up to 12% by weight." Furthermore, the CCPA focused on Ehrenreich's disclosure of using up to 48% by weight modifier, which would allow for a maximum of 52% by weight carbon. *Id.* at 544, 190 USPQ at 417-18.

The CCPA determined that Nitz's claim recitation of "up to 12% by weight" of a modifier was a material limitation due to the critical nature of having at least 80% carbon. The CCPA then determined that the count language "up to about 48% by weight" of the modifier was a material variation from Nitz's claimed invention. As such, the CCPA concluded that no interference-in-fact existed with respect to count 1. *Id.* at 545, 190 USPQ at 418.

As to count 2, the only issue on appeal was the materiality of Nitz's recitation that the carbonized layers of filamentary materials were "woundup" layers. The CCPA, however, determined that the structure of woundup layers was known in the prior art



and that the limitation was not necessary for the patentability of Nitz's claim. As such, the CCPA determined that Nitz's "woundup" limitation was not a material limitation of Nitz's claim and that an interference-in-fact existed with respect to count 2.

*Nitz* is consistent with the principle that there is no interference-in-fact when two parties are claiming "materially" different inventions. Further, *Nitz* is consistent with the principle that, for purposes of no interference-in-fact, claims of different scope can be separate patentable inventions even where one party's claim is literally encompassed by a second party's claim. Specifically, the CCPA found that Nitz's claimed "up to 12% by weight" modifier was a materially different invention from Ehrenreich's claimed "up to 48% by weight" modifier even though Nitz's claimed amount of modifier was literally encompassed by Ehrenreich's claimed amount of modifier.

## 2. *Aelony v. Arni*

*Aelony* concerned an appeal from a decision of the Board awarding priority of invention to Arni, the senior party. The subject matter of the interference was a method for purifying malononitrile. In particular, both parties treated an impure malononitrile with a conjugated diene in a Diels-Alder reaction to aid in the removal of impurities. Of note, *Aelony* taught the use of cyclopentadiene, a conjugated diene. In contrast, Arni did not specifically describe or claim cyclopentadiene as a suitable Diels-Alder reaction component for the removal of impurities. Rather, Arni specifically described eight other materials having conjugated double bonds as suitable for undergoing a Diels-Alder reaction for the removal of impurities. *Aelony v. Arni*, 547 F.2d 566, 567, 192 USPQ

486, 487 (CCPA 1977).

Before the Board, neither Aelony nor Arni took testimony. Rather, Aelony argued that there was no interference-in-fact between the parties. Specifically, Aelony argued that, for the purification method in dispute, cyclopentadiene was patentably distinct from the eight materials described by Arni. *Id.* at 568, 192 USPQ at 488. The Board did not agree. According to the Board, both parties carried out substantially the same process. Moreover, the Board found that Aelony's patentable distinctiveness argument was unsupported by the evidence. As such, the Board rejected Aelony's no interference-in-fact argument and awarded priority to senior party Arni. *Id.* at 568, 192 USPQ at 488.

In reviewing the merits of Aelony's appeal, the CCPA specifically rejected Aelony's argument that there was no interference-in-fact. The CCPA agreed with the Board "that the test of interference-in-fact is *not* whether two sets of claims overlap, but whether they are patentably distinct from **each other**." *Id.* at 570, 192 USPQ at 490 (bold emphasis added). According to the CCPA, the law contemplates that "where different inventive entities are concerned – that only one patent should issue for inventions which are either identical to or not patentably distinct from **each other**." *Id.* (bold emphasis added). The CCPA went on to state that "[m]oreover, we believe that there is ample precedent from this court for framing the test of interference in fact in terms of whether two sets of claims are patentably distinct from **each other**." *Id.* (bold emphasis added).

On the facts presented, the CCPA determined that "**both parties are claiming the same inventive concept**" and rejected Aelony's argument that there was no

interference-in-fact. *Id.* (bold emphasis added). In particular, the CCPA noted that both parties carried out the same process in which a conjugated diene material reacted with impurities according to the Diels-Alder reaction. Further, there was no dispute that the cyclopentadiene of Aelony and the eight conjugated dienes of Arni were all common Diels-Alder dienes. *Id.*

The decision in *Aelony* denied a motion for no interference-in-fact where two parties were claiming patentably indistinct inventions. Specifically, in deciding the question of no interference-in-fact, the CCPA focused its attention on whether or not the parties claims were patentably distinct from ***each other***. Where the claims of the parties are not patentably distinct from each other, the parties are claiming the same inventive concept and it is understood that only one patent should issue.

3. *Case v. CPC International, Inc.*

Case involved an appeal from a decision of a district court in a civil action under 35 USC §146 upholding the award of priority to CPC International, Inc., ("CPC") in an interference proceeding in the USPTO. The subject matter in the interference was directed to polyether polyols that consisted essentially of oxyalkylated polyalcohols and oxyalkylated polysaccharides. *Case v. CPC Int'l, Inc.*, 730 F.2d 745, 747, 221 USPQ 196, 198 (Fed. Cir. 1984).

The interference was provoked by CPC. To provoke the interference, CPC copied Case's patented claims. Of note, Case's patented claims specified that an oxyalkylated polyalcohol was present in an amount of 10 to 95% by weight and that an

oxyalkylated polysaccharide was employed in an amount of 5 to 95% by weight. During examination, CPC's claims were rejected as lacking sufficient written descriptive support under 35 U.S.C. § 112, 1st paragraph, for the copied weight limitations. The examiner, however, advised CPC to submit claims directed to "a polyether polyol which is the reaction product of starch and the various disclosed derivatives thereof with glycerin and propylene oxide." *Id.* In response to the examiner's rejection of the copied claims, CPC canceled the copied claims and submitted new claims that complied with the examiner's suggestion. *Id.* The newly added CPC claims, however, did not recite a particular weight limitation for the two oxyalkylated components. Moreover, when the interference was declared, the counts did not recite the weight limitations found in Case's patented claims.

Case presented numerous arguments challenging both the district court and the Board's award of priority to CPC. Of interest, Case argued that no interference-in-fact existed between Case's claims and CPC's. According to Case, the question of no interference-in-fact turned on whether or not the weight limitations present in Case's claims, but not CPC's claims, were material. The Federal Circuit agreed with this analysis.<sup>7</sup> *Id.* at 750, 221 USPQ at 200.

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<sup>7</sup>Specifically, the Federal Circuit stated:

Case challenges the declaration of the interference on the ground that no interference in fact exists. Relying on *Nitz v. Ehrenreich*, 537 F.2d 539, 190 USPQ 413 (CCPA 1976), Case argues that the question of interference in fact turns on whether or not the weight limitations present in the claims of Case's patent but omitted from the counts are material. We agree with this analysis but we see no departure by the board or the court in stating the law or applying it to the facts of this case.

According to the Federal Circuit, the question of materiality of the omitted limitations was one of fact. *Id.* The Court noted that both the district court and the Board had determined that the omitted weight limitations were not material as the range of proportions was quite broad and that Case's prosecution history demonstrated that the omitted limitations were not pertinent to patentability.

Additionally, Case argued that there was no interference-in-fact as the counts were unpatentable. Having reviewed Case's arguments, the Federal Circuit stated that:

***No interference in fact means that there is no interfering subject matter, that Case's patent is no impediment to granting CPC the claims of its application.*** It was Case's burden to prove that CPC claims a different invention from his own. Case cannot carry that burden with argument that the counts are unpatentable.

*Id.* (emphasis added). The Federal Circuit also stated that "[i]n sum, since the Case patent and the CPC application contain interfering subject matter, an interference proceeding was appropriate." *Id.* at 752, 221 USPQ at 202. The Court then went on to uphold the decision awarding priority of invention to CPC based upon its earlier application. *Id.*

As apparent from the decision in Case, the question of no interference-in-fact turns on whether or not the parties claims are "materially" different. The question of "material" differences being one of fact. Further, Case specifies that no interference-in-fact exists where one party's patent does not impede the grant of another party's claims.

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*Id.*

4. Summary of the CCPA and Federal Circuit Opinions on the Question of No Interference-in-Fact

An interference in fact involves interfering subject matter. As shown by the above decisions, there is no interfering subject matter, and thus, no interference-in-fact when the parties are claiming different patentable inventions. For example, there is no interference-in-fact when it is demonstrated that a party's claims are no impediment to the granting of an opponents claims. *Case*, 730 F.2d at 750, 221 USPQ at 200.

The cases analyzed above, *Nitz*, *Aelony* and *Case* and our interpretations thereof are all consistent with the no interference-in-fact decisions in *Almasi v. Strauss*, 589 F.2d 523, 200 USPQ 511 (CCPA 1979), and *Brailsford v. Lavet*, 318 F.2d 942, 138 USPQ 28 (CCPA 1963) as well as the interference-in-fact decision in *McCabe v. Cramblet*, 65 F.2d 459, 18 USPQ 71 (CCPA 1933).

B. The USPTO Rules and the Comments to the Rules Provide that No Interference-in-Fact Exists for Patentably Distinct Inventions

The interference rules were revised in 1984 to implement the interference provisions of the Patent Law Amendments Act of 1984 (Public Law 98-622). Notice of Final Rule, Patent Interference Proceedings, 49 Fed. Reg. 48416 (Dec. 12, 1984). As part of the rule revision, the Commissioner (now Director) promulgated several rules regarding the existence of an interference-in-fact. For example, the Commissioner promulgated 37 CFR Section 1.601(j)(definition of an interference-in-fact), Section 1.601(n)(definition of same and separate patentable inventions) and Section 1.633(b),

which authorized parties to file preliminary motions for judgment on the ground that there is no interference-in-fact.

In their present form, Rules 601(j), 601(n) and 633(b) read as follows:

Rule 601(j) An *interference-in-fact* exists when at least one claim of a party that is designated to correspond to a count and at least one claim of an opponent that is designated to correspond to the count define the same patentable invention.

Rule 601(n) Invention "A" is the *same patentable invention* as an invention "B" when invention "A" is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A". Invention "A" is a *separate patentable invention* with respect to invention "B" when invention "A" is new (35 U.S.C. 102) and non-obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A".

Rule 633(b) A motion for judgment on the ground that there is no interference-in-fact. A motion under this paragraph is proper only if the interference involves a design application or patent or a plant application or patent or no claim of a party which corresponds to a count is identical to any claim of an opponent which corresponds to that count. See §§1.637(a). When claims of different parties are presented in "means plus function" format, it may be possible for the claims of the different parties not to define the same patentable invention even though the claims contain the same literal wording.

Rules 601(j) and (n): 49 FR 48416, Dec. 12, 1984, effective Feb. 11, 1985; 50 FR 23123, May 31, 1985; revised, 60 FR 14488, Mar. 17, 1995; Rule 633(b): 49 FR 48416, Dec. 12, 1984, added effective Feb. 11, 1985; 50 FR 23124, May 31, 1985; revised, 60 FR 14488, Mar. 17, 1995, effective Apr. 21, 1995.

While the rules explicitly define when an *interference-in-fact* exists, the rules do not explicitly define "no" interference-in-fact. The comments to the rules, however, provide that the USPTO will continue to follow the decisions rendered in *Nitz*, *Aelony*

and *Case*. Notice of Final Rules, 49 Fed. Reg. 48416, 48421 (Dec. 12, 1984). As provided above, these three decisions demonstrate that the test for no interference-in-fact is grounded in patentable distinctness. *Nitz*, 537 F.2d at 545, 190 USPQ at 418; *Aelony*, 547 F.2d at 570, 192 USPQ at 490; *Case*, 730 F.2d at 750, 221 USPQ at 200. As such, a party may demonstrate that no interference-in-fact exists between two parties by proving that a first party's claim(s) are patentably distinct from the second party's claim(s).

The test for patentable distinctness is set forth in Rule 601(n), which states that an invention "A" is a separately patentable invention, i.e. patentably distinct, with respect to invention "B" when invention "A" is novel and non-obvious in view of invention "B" assuming invention "B" is prior art with respect to invention "A". For example, party A's claims are patentably distinct, i.e., separately patentable, when the party A's claims are no impediment to the granting of the opponents claims. See, e.g., *Nitz*, 537 F.2d at 544-45, 190 USPQ at 417-18 (No interference-in-fact where "up to 48%" modifier did not interfere with "up to 12%" modifier); *Case*, 730 F.2d at 750, 221 USPQ at 200 ("No interference in fact means that there is no interfering subject matter, that *Case*'s patent is no impediment to granting CPC the claims of its application.").

C. Lilly's Species Anticipates Dominating Genus Theory of Interference-in-Fact Lacks Merit

Lilly argues that for an interference in fact, the interference rules and comments require nothing more than a "species anticipates dominating genus" determination.



Thus, according to Lilly, its claimed species is the "same patentable invention" as UW's claimed genus based on the fact that its species would anticipate UW's genus.

Lilly states that the comments specifically inform the public that the test under Rule 601(n) for determining the "same" patentable invention could not be applied two ways, i.e. a party need only demonstrate "one-way" anticipation or obviousness for an interference-in-fact. Specifically, Lilly has argued that:

The regulations of the PTO, 37 CFR §1.601(n), having the force and effect of law, require nothing more than the "species anticipates dominating genus" determination to establish the existence of an interference-in-fact. Indeed, the official commentary issued by the PTO at the time the rules were adopted made clear that the test for the "same patentable invention" under 37 CFR §1.601(n) could not be applied two ways. 49 FR 48416 at 48434 (Dec. 12, 1984). ***As stated by the PTO in the administrative history for the regulations, the "same patentable invention" [test] . . . under §1.601(n) . . . [is] not intended to be 'applied in a mutuality sense.'***" [Footnote omitted].

(Lilly Preliminary Motion 1, Paper No. 22, p. 5, emphasis added). Additionally, responding to comments from UW, Lilly stated:

In response to a specific question posed by one commentator in 1984 asking whether the PTO's proposed Rule 1.601(n) would involve a one-way or two-way patentability determination, the Office responded in unequivocal terms that a one-way test would be applied. Notice of Final Rules, 49 Fed. Reg. 48,416, 48,433 (1984). Six years later this rule was restated by the Board in *Chiong v. Roland*, 17 U.S.P.Q.2d 1541, 1544 (Bd. Pat. App. & Int. 1990) ("As pointed out in the Notice, supra at 48433, ***the standard of patentability will not be applied on a 'mutual basis.'***")

(Lilly Reply 1, Paper No. 30, pages 8-9, emphasis added). This panel has reviewed the comments to the rules and finds no merit in Lilly's "species anticipates dominating genus" test.

Lilly has relied upon two specific comments to the rules. The comments may be

found at pages 48,433-48,434 of the Notice of Final Rules, 49 Fed. Reg. 48,416 (Dec. 12, 1984). Provided below are the full paragraphs ((1) & (2)) from which Lilly's quoted material is derived:

- (1) With respect to paragraph (1) of the comment, the standard of patentability will not be applied "on a mutual basis." **Thus, if a species is patentable over a genus, the species is a "separate patentable invention" from the genus.** Compare *In re Taub*, 348 F.2d 556, 146 USPQ 384 (CCPA 1965) (fluorine species might be patentable over genus of Markush group of hydrogen and halogen). A first count to a genus and a second count to a species which is patentable over the genus may properly appear in an interference. See e.g., Example 4. The comment suggests that if "such mutuality is not applied \* \* \* then a number of irreconcilable anomalies \* \* \* will be manifest." The urged "irreconcilable anomalies" are not readily apparent to the PTO.

(Fed. Reg., p. 48433, underline emphasis added denotes Lilly's cited commentary, bold emphasis added to highlight application of Rule 601(n) for genus/species situations).

- (2) Analysis of Commentator's Example A. Example A does not describe any practice under these rules, because "same patentable invention" and "separate patentable invention" under § 1.601(n) are not intended to be "applied in a mutuality sense." **Where a first count is to a genus and a second count is to a species within the scope of the genus, there may be two counts if the species is separately patentable from the genus.** The species is "invention A" referred to in § 1.601(n); the genus is "invention B" referred to in § 1.601(n).

(Fed. Reg., p. 48434, underline emphasis added denotes Lilly's cited commentary, bold emphasis added to highlight application of Rule 601(n) for genus/species situations).<sup>8</sup>

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<sup>8</sup>While not specifically mentioned by Lilly, Lilly's relied upon comments were written in response to questions concerning whether or not the standard of patentability would be applied on a mutual basis in determining whether to add an additional count. Each count, of course, must be directed to a separate patentable invention. 37 CFR §1.601(f). In other words, the comments responded to a question of whether the USPTO would require that Invention A be separately patentable from Invention B considered as prior art and Invention B be separately patentable from Invention A

The comments to the rules regarding the test for "same or separate patentable inventions" are highly relevant and material to the issues raised in this interference as they inform the public that a *genus* and a patentably distinct *species* are separate patentable inventions. If the rule were only applied in the manner suggested by Lilly, i.e., nothing more than species anticipates dominating genus, then the comments to the rule that a species that is patentable over a genus is a "separate patentable invention" from the genus would make no sense. Specifically, Lilly's argument would have us determine that the species and dominating genus defined both the same patentable invention and, at the same time, a separate patentable invention. Consistent with the precedential Federal Circuit and CCPA opinions mentioned above, the comments to rules explicitly provide that a patentably distinct species and a dominating genus are ***separately patentable*** inventions.

2. Lilly and UW's Corresponding Claims Are Separate Patentable Inventions  
As UW's Corresponding Claims Do Not Impede the Grant of Lilly's  
Corresponding Claims

The test for no interference-in-fact is whether or not the parties are claiming separately patentable inventions. In applying this test, we begin with a comparison of the parties' corresponding claims as there exists a rebuttable presumption that each

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considered as prior art), in order for an interference to have both a species count and a genus count. The answer to this was no. Notice of Final Rules, 49 Fed. Reg. 48,416, 48432-434 (Dec. 12, 1984). Note, the test for no interference-in-fact and the addition of new count is essentially the same, i.e., patentable distinctness. See, e.g., *Hester v. Allgeier*, 646 F.2d 513, 521, 209 USPQ 370, 378 (CCPA 1982).

claim designated to correspond to a count defines the same patentable invention as all other claims designated to correspond to the count. See, e.g., *Orikasa v. Oonishi*, 10 USPQ2d 1996, 2004 (Comm'r Pat. & Trademark 1989).

Count 1 is the sole count in interference. As declared, UW claim 3 and Lilly claims 1-82 and 84-90 correspond to Count 1. Additionally, Lilly has requested that UW claim 1 be designated as corresponding to Count 1. For purposes of determining if there is no interference-in-fact between the parties, we will assume that Lilly is correct in stating that UW claim 1 corresponds to Count 1. Accordingly, we compare UW claims 1 and 3 with Lilly's corresponding claims to determine whether the parties are claiming separately patentable inventions.

A. Anticipation and Obviousness

A prima facie case of obviousness is established when the teachings of the prior art would have suggested the claimed subject matter to a person of ordinary skill in the art with a reasonable likelihood of success of achieving the suggested invention. *In re Dow Chem.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). Any motivation or suggestion to modify the prior art references must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed Cir. 1995); *In re Gorman*, 933 F.2d 982, 986-87, 18 USPQ2d 1885, 1888, (Fed. Cir. 1991).

A claim to a specific cDNA is not made obvious by mere knowledge of a desired protein sequence and methods for generating the various cDNA that have the potential

to encode that protein. *Cf., Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1567, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997)("We had previously held that a claim to a specific DNA is not made obvious by mere knowledge of a desired protein sequence and methods for generating the DNA that encodes that protein."); *In re Deuel*, 51 F.3d 1552, 1558, 34 USPQ2d 1210, 1215 (1995)("A prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein."); *In re Bell*, 991 F.2d 781, 787, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993)("It may be true that, knowing the structure of the protein, one can use the genetic code to hypothesize possible structures for the corresponding gene and that one thus has the potential for obtaining that gene. . . . Therefore, given the nearly infinite number of possibilities suggested by the prior art, and the failure of the cited prior art to suggest which of those possibilities is the human sequence, the claimed sequences would not have been obvious.").

Anticipation is the epitome of obviousness. *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983) (citing *In re Fracalossi*, 681 F.2d 792, 215 USPQ 569 (CCPA 1982)). Anticipation is established only if each and every element of a properly construed claim is found, either expressly or inherently described, in a prior art reference. *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1624-1625 (Fed. Cir. 1996).

B. UW Claim 3 is Patentably Distinct from Lilly's Corresponding Claims

UW claim 3 is directed to a plasmid or transfer vector that comprises the cDNA sequence depicted in UW Figure 3, from base pair 127 to base pair 1383. Lilly claim 1 corresponds to Count 1 and requires a constructed DNA compound that encodes a polypeptide with human protein C activity wherein the coding strand comprises several distinct cDNA species. Lilly claims 2-75, 77-80 and 84-88 all depend from Lilly claim 1 or require a DNA compound of Lilly claim 1. Of the remaining Lilly corresponding claims, Lilly claim 76 is directed towards several "intermediate" plasmids that lack the protein C cDNA, while Lilly claims 81 and 82 relate to recombinant DNA sequences that comprise the coding sequence for the active light chain of human protein C. Thus, as it is readily apparent that Lilly's intermediate plasmids are patentably distinct from UW claim 3, the proper comparison for patentable distinctness is between the cDNA species of UW claim 3 and the cDNA species recited in Lilly claim 1 and Lilly claims 81 and 82.<sup>9</sup>

The sequence claimed in UW claim 3 is a cDNA sequence having at least 1257 base pairs, i.e., 419 codons (three base pairs to a codon), that encode a protein of 419 amino acids. For such a sequence, the odds of randomly changing a single codon are 1 in 419, changing any two codons at random is 1 in 175,142 ( $419 \times 418$ ), changing any three codons at random is 7,303,214 ( $419 \times 418 \times 417$ ), etcetera. (See generally,

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<sup>9</sup>While Lilly's corresponding claims encompass several distinct species of cDNA, for reasons of convenience we refer to Lilly claims as "species" claims as opposed to "genus" or "subgenus" claims.

Paper No. 17, pages 5-6, ¶ 11).

Comparing the sequence of UW claim 3 (UW Fig. 3, bp 127 to bp 1383) with the pertinent portions of the cDNA sequence of Lilly claim 1, two nucleotide differences are revealed in the coding region:

- 1) UW Fig. 3, nucleotide 423 (third position of codon 99) is thymine ("T"), whereas Lilly's is guanine ("G").
- 2). UW Fig. 3, nucleotide 768, (third position of codon 214) is cytosine ("C"), whereas Lilly's is thymine ("T").

(Paper No. 17, p. 3, ¶6; Paper No. 27, p. 3, admitting UW facts 6-16.). The parties agree that:

The particular differences in the nucleotide sequences that occur between the sequences of Foster [UW] claim 3 and Bang [Lilly] claim 1 within two different codons could not have been predicted in advance based on knowledge of either Bang's nucleotide or amino acid sequences alone.

(Paper No. 17, p. 5, ¶11; Paper No. 27, p. 3, admitting UW facts 6-16.).

When there is a specific, structurally related prior art compound, the question of obviousness is whether the prior art suggested the specific modifications necessary to achieve the claimed compound. *In re Deuel*, 51 F.3d at 1557-58, 34 USPQ2d at 1214. On the record presented, there is insufficient evidence that Lilly's claimed sequence, taken in combination with the prior art, would have suggested the specific modifications to nucleotide 423 and nucleotide 768 such that one skilled in the art would arrive at the cDNA sequence described by UW claim 3. Additionally, there is insufficient evidence that one skilled in the art presented with the amino acid sequence of human protein C would have been guided to form the specific cDNA sequence recited in UW claim 3. *In re Deuel*, 51 F.3d at 1559, 34 USPQ2d at 1215-16 (Due to enormous number of DNA

molecules encoding for the protein, disclosure of amino acid sequence did not render particular DNA molecules encoding the protein obvious). We conclude that Lilly claim 1 and UW claim 3 are patentably distinct as Lilly claim 1 does not render UW claim 3 obvious. Furthermore, Lilly claim 1 does not anticipate UW claim 3 as Lilly claim 1, taken in light of the prior art, fails to teach all the limitations of UW claim 3.

Lilly claims 81 and 82 are directed to the coding sequence for the active light chain of human protein C. Lilly claim 81 does not specifically recite the structure of the coding sequence whereas Lilly claim 82 specifically sets forth the coding strand. The coding strand in Lilly claim 82 contains 465 base pairs, i.e., 155 codons. In contrast, UW claim 3 is directed to the cDNA encoding protein C and contains 1257 base pairs, i.e., 419 codons. The amino acid sequence of human protein C light chain, such as that recited in Lilly claim 81, and a particular DNA encoding that amino acid sequence, such as that provided in Lilly claim 82, do not provide sufficient information for one skilled in the art to predict the particular DNA sequence of UW claim 3. (Paper No. 17, p. 11, ¶21; Paper No. 27, p. 3, admitting UW facts 18-21). As Lilly claims 81 and 82 fail to teach or suggest the cDNA of UW claim 3, we conclude that UW claim 3 is patentably distinct from Lilly claims 81 and 82.

C. Lilly's Corresponding Claims Are Patentably Distinct from UW Claim 1

UW claim 1 is directed to a plasmid or transfer vector that comprises cDNA coding for a human protein C. According to Lilly, there are two possible claim constructions for UW claim 1. (See, Paper No. 30, pages 4-5). First, Lilly contends that



UW claim 1 must be construed as "limited to the specific allelic cDNA sequence disclosed in the UW '529 Patent, as is claim 3 of the UW '529 Patent" and that "claim 1 of the UW '529 Patent is essentially equivalent to claim 3 of the UW '529 Patent." (Paper No. 27, p. 7 and p. 9 and Paper No. 30, p. 4). Alternatively, Lilly argues that it is expected that UW will contend that claim 1 is generic and encompasses not only the cDNA sequence that UW discovered, but also the cDNA sequence discovered by Lilly. (See, Paper No. 27, p. 9). It is not necessary for us to determine whether UW claim 1 is as broad or as narrow as Lilly contends. There is no interference-in-fact under either claim construction. If we construe UW claims 1 and 3 as "essentially equivalent," there is no interference-in-fact as Lilly's corresponding claims do not teach or suggest the cDNA of UW claim 3 and would likewise not teach or suggest an "essentially equivalent" cDNA of UW claim 1. Specifically, Lilly's corresponding claims do not teach or suggest the particular number and location of the polymorphisms in the cDNA of UW claim 3 nor would they teach or suggest a such polymorphisms in a similarly construed claim.

If we construe UW claim 1 to be a generic claim covering any cDNA sequence that encodes human protein C, there is still no interference-in-fact. So construed, UW claim 1 would encompass thousands of possible sequences. Given such a vast number of possible sequences encompassed by a broadly construed UW claim 1, there would need to exist some suggestion or teaching in the prior art that guided one skilled in the art to the specific species claimed by Lilly. See *In re Baird*, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994)(Prior art teaching of "vast number" of possible diphenol

compounds did not teach or suggest the selection of Baird's claimed bisphenol A); *In re Belle*, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993)(DNA sequence would not have been obvious in view of prior art reference that taught a vast number of possibilities but did not teach or suggest why, among all those possibilities, one would seek the claimed sequence). The evidence presented fails to teach or suggest the selection of Lilly's claimed cDNA species from among the vast number of potential sequences that would be encompassed by a broadly construed UW claim 1. As UW claim 1, taken in light of the prior art, does not fairly teach or suggest Lilly's specifically claimed species, Lilly's claimed species are patentably distinct from a broadly construed UW claim 1. As a patentably distinct species is a "separate patentable invention" from its dominating genus, there is no interference in fact between a broadly construed UW claim 1 and Lilly's corresponding claims.

Based on the facts presented, neither UW claim 1 nor UW claim 3 impedes the grant of Lilly's corresponding claims. *Case*, 730 F.2d at 750, 221 USPQ at 200. As UW's allegedly corresponding claims do not impede the issuance of Lilly's corresponding claims, there is no interference-in-fact. UW Preliminary Motion 1 for no interference-in-fact is **granted**.

3. Lilly Did Not Have Authorization to Set Its Own Time Period for Filing Motions to Add or Substitute a Count

Lilly had a full and fair opportunity to file motions responding to UW's motion for no interference-in-fact. Specifically, UW's motion was filed under Rule 633(b). Rule 633(i) permits a party to respond to such a motion by filing a motion to: (i) redefine the

interfering subject matter (633(c)); (ii) substitute a different application (633(d)); or (iii) add a reissue application to the interference (633(h)). As such, Lilly had the opportunity to file a motion to redefine the interfering subject matter by adding or substituting a count or seek to have the claim correspondence changed. See, 37 CFR §§ 1.633(b), (c) and (i). Rather than file a motion to add or substitute a count, Lilly stated that:

If this interference proceeds, further redefinition of the interfering subject matter would be necessary and desirable. For example, some modification of the Count itself will be necessary under 37 C.F.R. § 1.633(c)(1) so that it encompasses the subject matter of the involved Bang reissue claims currently designated as corresponding to the count. Otherwise, Lilly could be improperly denied the opportunity to present its best priority proofs. [Citation omitted]. Such modification of the Count is not necessary to resolve the interference-in-fact issue that is the subject of this special motion period, which merely turns on the "same patentable invention" relationship between the respective claims of the parties designated as corresponding to the Count. If a Preliminary Motion Period is set, Lilly will present an appropriate motion to modify the Count itself to exercise its right to have a count representing its "best proofs." In the same vein, Lilly will move during the Preliminary Motions Period to appropriately further modify the scope of the interference by designating the appropriate claims of the parties as corresponding to the Count.

(Lilly Preliminary Motion 1, Paper No. 22, p. 6, fn. 2).

Under the rules, a preliminary motion under §§ 1.633 (a) through (h) shall be filed within a time period set by an APJ . Moreover, the time for filing motions under § 1.633 (i) is twenty (20) days after service of the initial motion under rule 633(a), (b), (c)(1) or (g), unless otherwise ordered by an APJ. 37 CFR §§ 1.636 (a) and (b).

In this case, an APJ set a specific time period for filing motions for no interference-in-fact or for judgment of unpatentability under 35 U.S.C. § 135(b). (Order, Paper No. 16). The APJ also set a specific time period for filing responsive rule 633(i) and (j) preliminary motions. (Order, Paper No. 16). As noted above, Lilly has chosen to

*sua sponte* set its own schedule for submitting motions to redefine the interfering subject matter.

Lilly's failure to comply with the times set by the APJ undermines the APJ's ability to secure a "just, speedy, and inexpensive" determination of this interference. By failing to timely file its motions to redefine the interfering subject matter, Lilly has avoided the difficult and complex question of what a proper count and claim correspondence would be if this interference were to proceed. Further, if Lilly had timely filed its "necessary and desirable" motions to redefine the interfering subject matter, Lilly's motions may have provided additional evidence regarding the existence of an interference-in-fact or lack thereof. Lilly instead chose a more limited approach and is subject to the consequences of its choices.

4. The Panel Will Not Exercise Its Discretion Under Rule 641 to Review the Patentability of UW Claim 1

Lilly has argued that the issue of UW's written descriptive support for UW claim 1 is presently before the Board. This is not the case. Neither Lilly nor UW has briefed this particular issue. Moreover, as the panel has determined that there is no interference-in-fact between UW and Lilly, no Rule 1.633(a) patentability motions will be accepted from the parties. This is not to say that the panel has determined that UW claim 1 is patentable, but rather it is a recognition that Lilly will not be afforded the opportunity to submit unpatentability motions where there is no interference-in-fact. *Berman v. Housey*, 2002 U.S. App. LEXIS 10256 at \*24 (Fed. Cir. 2002)(Refusal by Board to address issues of priority and patentability once it determined that there is no

interference-in-fact is supported by sound policy considerations).

During the course of an interference, if an APJ become aware of a reason why a claim designated as corresponding to the count may not be patentable, the APJ has the discretion to enter an order notifying the parties of the reasons and set a time for each party to present its views. 37 CFR § 1.641. This interference was declared based, in part, on Lilly's allegations that a nucleotide sequence encoding protein C deposited by UW was identical to that of Lilly's. These allegations proved to be erroneous, albeit inadvertently. Given the circumstances of this interference, the panel chooses not to exercise its discretion under Rule 1.641 and explore the patentability or unpatentability of UW claim 1.

5. Lilly Contingent Miscellaneous Motion 2 is Moot

Lilly filed a motion seeking leave to belatedly file a preliminary statement. (Lilly Contingent Miscellaneous Motion 2, Paper No. 41, p. 1). Lilly's motion is contingent on the determination that there is an interference-in-fact. As we have granted UW Preliminary Motion 1 for no interference-in-fact, Lilly's miscellaneous motion is moot.

6. Additional Comments

Lilly has argued that they have no other remedy in the USPTO. (Paper No. 27, p. 11). According to Lilly, a reexamination of UW's 529 patent is not available as Lilly's '624 patent was cited during the prosecution of UW's patent and UW overcame this rejection by filing a declaration under 37 CFR § 1.131. As such, Lilly concludes that the

issue of Lilly's alleged work under § 102(g) should be resolved in an interference proceeding. Lilly also argues that the failure to recognize an interference-in-fact under the present circumstances leads to the "absurd, inequitable, and unlawful" result that Lilly's practice of its own prior invention may be alleged to infringe UW's claims.

The existence or nonexistence of another remedy within the USPTO is not a basis for continuing an interference where none exists. Should Lilly believe that an actual controversy exists between the UW '529 patent and Lilly's activities, Lilly may file a declaratory judgment action in district court.

#### ORDER

Upon consideration of the motions, it is:

**ORDERED** that UW Preliminary Motion 1 for no interference-in-fact is ***granted***.


**FURTHER ORDERED** that there is no interference-in-fact between claims 1 and 3 of UW, U.S. Patent No. 5,302,529 and claims 1-82 and 84-90 of Lilly, U.S. Application No. 09/185,663.

**FURTHER ORDERED** that Lilly Preliminary Motion 1 to designate an additional patent claim is ***moot***.

**FURTHER ORDERED** that Lilly Contingent Miscellaneous Motion 2 for leave to belatedly file a preliminary motion is ***moot***.

**FURTHER ORDERED** that if there is a settlement agreement, attention is directed to 35 U.S.C. § 135(c) and 37 CFR § 1.661.

**FURTHER ORDERED** that a copy of this final decision shall be placed and given  
a paper number in the file of Foster, U.S. Patent No. 5,302,529 and Bang, U.S.  
Application No. 09/185,663.

  
RICHARD E. SCHAFER  
Administrative Patent Judge

  
RICHARD TORCZON  
Administrative Patent Judge

  
MICHAEL P. TIERNEY  
Administrative Patent Judge

BOARD OF  
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INTERFERENCES

INTERFERENCE  
TRIAL SECTION

cc (first-class mail):

Counsel for University of Washington  
(Zymogenetics, Inc., exclusive  
licensee):  
Edward J. Keeling  
Steven W. Parmalee  
TOWNSEND AND TOWNSEND AND  
CREW, LLP  
2 EMBARCADERO CTR FL 8  
SAN FRANCISCO CA 94111-3834  
  
Tel: 415-576-0200  
Fax: 415-576-0300

Counsel for Eli Lilly & Co.:  
Charles E. Lipsey  
Kenneth J. Meyers  
FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.  
1300 I ST NW STE 700  
WASHINGTON DC 20005-3315  
  
Tel: 202-408-4000  
Fax: 202-408-4400



## INTERFERENCE DIGEST

Interference No. 104,733

Paper No. 27

Name: Nils U. Bang et al.

Serial No.: 09/185,663

Patent No.

Title: VECTORS AND COMPOUNDS FOR EXPRESSION OF HUMAN PROTEIN C

Filed: 11/04/98

Interference with Foster et al.

### DECISION ON MOTIONS

Administrative Patent Judge, \_\_\_\_\_ Dated, \_\_\_\_\_

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### FINAL DECISION

Board of Patent Appeals and Interferences, Adverse Dated, 6/14/02

Court, \_\_\_\_\_ Dated, \_\_\_\_\_

### REMARKS

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This should be placed in each application or patent involved in interference in addition to the interference letters.

Filed by: APJ Torczon  
BOX INTERFERENCE  
WASHINGTON DC 20231  
T: 703-308-9797  
F: 703-305-0942

This paper is not binding precedent of the board

Paper No. 1

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

BOARD OF REGENTS OF THE  
UNIVERSITY OF WASHINGTON  
(5,302,529),

Junior Party,

v.

ELI LILLY & CO.  
(09/185,663),

Senior Party.

MAILED

AUG 7 - 2001

PAT. & T.M. OFFICE  
BOARD OF PATENT APPEALS  
AND INTERFERENCES

Patent Interference No. 104,733

NOTICE DECLARING INTERFERENCE  
(37 C.F.R. § § 1.611)

**Part A. Declaration of interference**

An interference is declared (35 U.S.C. § 135(a)) between the above-identified parties.

Details of the patent, reissue application, count, and claims designated as corresponding or not corresponding to the count appear in Parts E and F of this NOTICE DECLARING INTERFERENCE.

**Part B. Administrative patent judge assigned  
to administer the interference**

Richard Torczon has been designated to handle the interference. 37 C.F.R. § § 1.610.

**Part C. Standing order**

=

A Trial Section STANDING ORDER accompanies this NOTICE DECLARING INTERFERENCE. The STANDING ORDER applies to this interference.

**Part D. Conference call to set dates**

A telephone conference call to set dates for action in this interference is scheduled for **2 p.m. (Eastern) on 3 October 2001.** (The Board will initiate the call.)

No later than **two business days** prior to the conference call, each party shall file and serve by facsimile a list of the preliminary motions the party intends to file. See § 17 of the STANDING ORDER.

A copy of a "sample" order setting times for taking action during the preliminary motion phase of the interference accompanies this NOTICE DECLARING INTERFERENCE. Counsel are encouraged to discuss the order by telephone prior to the telephone conference call and to reach an agreement as to dates for taking action. A typical preliminary motion period lasts approximately nine months. Counsel should be prepared to justify any request for a shorter or longer period.

**Part E. The parties to this interference**

Junior Party

**Inventors:** Donald C. FOSTER of Seattle and  
Earl W. DAVIE of Bellevue, both of WASHINGTON

**Patent:** 5,302,529, issued 12 April 1994 (07/512,961, filed 23 April 1990)

**Title:** DNA sequence coding for protein C

**Priority benefit:** 06/766,109, filed 15 August 1985 (4,968,626, issued 6 November 1990)

**Assignee:** The Board of Regents for the University of Washington

**Attorneys:** See last page

**Address:** See last page

Senior Party

**Inventors:** Nils U. BANG of Indianapolis, INDIANA,  
Robert J. BECKMANN of Indianapolis, INDIANA,  
S. Richard JASKUNAS of Natick, MASSACHUSETTS,  
Mei-Huei T. LAI of Carmel, INDIANA,  
Sheila P. LITTLE of Indianapolis, INDIANA,  
George L. LONG of Burlington, VERMONT, and  
Robert F. SANTERRE of Zionsville, INDIANA

**Reissue** 09/185,663, filed 4 November 1998

**Application:** (4,775,624, issued 4 October 1988; 06/699,967, filed 8 February 1985)

**Title:** Vectors and compounds for expression of human protein C

**Priority benefit:** None

**Assignee:** Eli Lilly & Co.

**Attorneys:** See last page

**Address:** See last page

**Part F. Count and claims of the parties**

Count 1

A plasmid or transfer vector of Foster claim 3.<sup>1</sup>

The claims of the parties are:

University of Washington: 1-4

Eli Lilly & Co.: 1-82 and 84-90

The claims corresponding to Count 1:

University of Washington: 3

Eli Lilly & Co.: 1-82 and 84-90<sup>2</sup>

The claims not corresponding to Count 1:

University of Washington: 1, 2, and 4

Eli Lilly & Co.: None

---

<sup>1</sup> 3. The plasmid or transfer vector of claim 1, comprising the cDNA sequence of [Foster] FIG. 3, from bp 127 to bp 1383.

1. A bacterial plasmid or bacteriophage transfer vector comprising cDNA coding for the amino acid sequence of FIG. 3, starting with alanine, number 1, and ending with proline, number 419, said cDNA sequence coding for human protein C.

<sup>2</sup> This determination is based on Bang's representation in 663 Paper No. 18 at 11.

**Part G. Heading to be used on papers**

The following heading shall be used on all papers filed in the interference. See § 18 of  
the STANDING ORDER.

-----  
Filed on behalf of: Party \_\_\_\_\_ Paper No. \_\_\_\_\_<sup>3</sup>

By:               Name of lead counsel  
                  Name of backup counsel  
                  Street address  
                  City, State, and ZIP Code  
                  Tel:  
                  Fax:

UNITED STATES PATENT AND TRADEMARK OFFICE

\_\_\_\_\_  
BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES  
(Administrative Patent Judge Torczon)

\_\_\_\_\_  
BOARD OF REGENTS OF THE  
UNIVERSITY OF WASHINGTON  
(5,302,529),

Junior Party,

v.

ELI LILLY & CO.  
(09/185,663),

Senior Party.

\_\_\_\_\_  
Patent Interference No. 104,733

\_\_\_\_\_  
TITLE OF PAPER

\_\_\_\_\_  
<sup>3</sup> Leave blank for the Board to insert the paper number when the paper is entered into the administrative record.

**Part H. Summary of dates for taking action**

Dates and times for taking action are set in the following sections of the STANDING

**ORDER:**

1.    § 7 - date for identifying lead and backup counsel.
2.    § 8 - date for identifying any real party in interest.
3.    § 9 - date for requesting copies of involved and benefit applications and patents.
4.    § 17 - date for filing list of preliminary motions to be filed.
5.    § 19 - date for accomplishing certain discovery.
6.    § 20 - date for filing clean copy of claims.
7.    § 21 - date for filing clean copy of claims in cases with drawings or claims containing a means-plus-function limitation.
8.    § 23 - times for filing oppositions to Rule 635 motions and times for filing replies to oppositions.
9.    § 33 - time for objecting to admissibility of evidence.
10.   § 34 - time for serving supplemental affidavits or evidence to respond to an objection to admissibility of evidence.
11.   § 35 - times when cross-examination can take place.
12.   § 45 - times for taking action with respect to settlement discussions

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

#46  
SOLICITOR

AUG - 8 2002

*Eli Lilly & Co., Appellant,*

U.S. PATENT & TRADEMARK OFFICE

v.

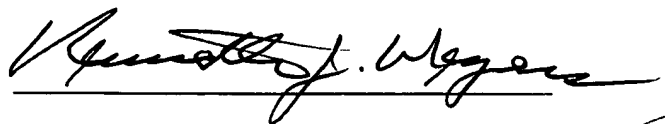
APPEAL OF DECISION

*Board of Regents of the  
University of Washington, Appellee.*

Eli Lilly & Co. hereby appeals to the court for review of the Judgment  
Pursuant to 37 C.F.R. § 1.640 of the Board of Patent Appeals and  
Interferences entered on June 11, 2002.

The Appellant received the decision of the Board of Patent Appeals  
and Interferences on June 14, 2002.

Date: August 8, 2002



Charles E. Lipsey  
Kenneth J. Meyers  
FINNEGAN, HENDERSON,  
FARABOW, GARRETT &  
DUNNER, L.L.P.  
1300 I Street, N.W.  
Washington, D.C. 20005  
(202) 408-4000 Phone  
(202) 408-4400 Fax



CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing APPEAL OF DECISION was served by prepaid Federal Express courier service on the Appellee, Board of Regents of the University of Washington, through its attorney of record on this the 8<sup>th</sup> day of August, 2002, as follows:

Henry N. Wixon, Esq.  
Hale and Dorr, L.L.P.  
1455 Pennsylvania Ave., N.W.  
Washington, D.C. 20004  
Tel. No.: (202) 942-8459  
Fax No.: (202) 942-8484  
E-mail: henry.wixon@haledorr.com

By:   
Ann Bennett

CEL- [redacted] - DUK-DCD

The opinion in support of the decision being entered today is not binding precedent of the Board.

Filed by: Trial Section Motions Panel  
Box Interference  
Washington, D.C. 20231  
Tel: 703-308-9797  
Fax: 703-305-0942

Filed: June 11, 2002

Paper 43  
**RECEIVED**

JUN 14 2002

2021-8673  
UNITED STATES PATENT AND TRADEMARK OFFICE

FINNEGAN, HENDERSON,  
FABER, GARRETT & DUNNER, LLP.

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

BOARD OF REGENTS OF THE  
UNIVERSITY OF WASHINGTON  
(5,302,529),

Junior Party,  
v.

ELI LILLY & CO.  
(09/185,663),

Senior Party.

**MAILED**

JUN 11 2002

PAT. & T.M. OFFICE  
BOARD OF PATENT APPEALS  
AND INTERFERENCES

Interference No. 104,733

Before SCHAFER, TORCZON, and TIERNEY, Administrative Patent Judges.

TIERNEY, Administrative Patent Judge.

**JUDGMENT**  
(PURSUANT TO 37 CFR § 1.640)

This interference is before a motions panel for a decision on preliminary motions.  
Oral argument took place on April 3, 2002. No transcript of the oral argument is available as the parties did not provide a court reporter.

Dhr4  
6-14-02  
C

The opinion in support of the decision being  
entered today is not binding precedent of the Board.

Paper 45

Filed by: Trial Section Motions Panel  
Box Interference  
Washington, D.C. 20231  
Tel: 703-308-9797  
Fax: 703-305-0942

Filed: June 11, 2002

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

---

BOARD OF REGENTS OF THE  
UNIVERSITY OF WASHINGTON  
(5,302,529),

Junior Party,  
v.

ELI LILLY & CO.  
(09/185,663),

Senior Party.

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Interference No. 104,733

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Before SCHAFER, TORCZON, and TIERNEY, Administrative Patent Judges.

TIERNEY, Administrative Patent Judge.

**JUDGMENT**  
(PURSUANT TO 37 CFR § 1.640)

This interference is before a motions panel for a decision on preliminary motions.  
Oral argument took place on April 3, 2002. No transcript of the oral argument is  
available as the parties did not provide a court reporter.

I. Summary of the Decision

The issues presented in this interference are straightforward. University of Washington ("UW") has requested a judgment of no interference-in-fact. As permitted by the rules, Lilly has requested that, prior to determining the question of no interference-in-fact, we designate an additional UW claim as corresponding to the count.

The Federal Circuit has stated that no interference-in-fact means that there is no interfering subject matter. Thus, no interference-in-fact means that the parties are claiming different patentable inventions, an example of which occurs when the claimed subject matter of a party's patent would not impede the granting of an applicant's claims. As such, the issues raised by the parties are simply a question of whether or not UW's patent claims would prevent the issuance of Lilly's claims.

There is a rebuttable presumption that each claim designated as corresponding to a count defines the same patentable invention as all other claims designated as corresponding to the count. Indeed, 37 CFR § 1.601(j) states that:

An "interference-in-fact" exists when at least one claim of a party that is designated to correspond to a count and at least one claim of an opponent that is designated to correspond to the count define the same patentable invention.

Accordingly, in analyzing the question of no interference-in-fact, we compare a party's corresponding claims to an opponent's corresponding claims. Specifically, we presume that the subject matter of a party's corresponding claims are "prior art" to an opponent's corresponding claims in order to determine whether or not the parties invented the same patentable invention. Where a party's corresponding claims are separately

patentable from an opponent's corresponding claims, a judgment of no interference-in-fact is appropriate.

Presently, UW is involved in this interference on the basis of UW claim 3, a "species" claim. Lilly has requested that UW claim 1, a "genus" claim, be added to the interference as corresponding to Count 1, the sole count in the interference.

UW's corresponding "species" claim does not anticipate or render obvious any of Lilly's corresponding claims. Nor would UW's "genus" claim, should it correspond, anticipate or render obvious any of Lilly's corresponding claims. Accordingly, UW's species and genus claims are not an impediment to granting Lilly's corresponding claims. As such, we grant UW's motion for no interference-in-fact.

The parties have entered into a vigorous dispute as to the relative merits of the Board's precedential decision in *Winter v. Fujita*, 53 USPQ2d 1234 (Bd. Pat. App. & Int. 1999). As the questions presented in this interference do not require our reliance on any issue resolved in *Winter*, we need not address the parties' comments regarding that decision.

## II. The Technology in Question

Generally, the technology involved in this interference relates to cDNA that codes for a polypeptide ("protein") having human protein C activity. Protein C is a zymogen, or inactive precursor, of a plasma serine protease, activated protein C ("APC"). Specifically, protein C is formed as a single-chain polypeptide that undergoes processing to form a two-chain molecule having a heavy chain and a light chain that are

connected via disulfide bonds. This two-chain intermediate is converted to APC by cleaving a 12-residue peptide from the heavy chain. APC plays a critical role in the regulation of blood coagulation as it represents a physiological mechanism for blood anticoagulation.<sup>1</sup>

To understand the nature of cDNA it is necessary to understand the function of DNA. DNA ("deoxyribonucleic acid") is the blueprint of an organisms genetic makeup as it is the primary genetic material. In an organism, a portion of DNA, a gene, may undergo transcription to form mRNA (messenger ribonucleic acid). The mRNA in turn, may then be translated to form a polypeptide, e.g., an enzyme or a structural protein.

DNA is the term used to represent the complex macromolecules made up of nucleotide units. A nucleotide unit is characterized by a specific combination of a base, a sugar and a phosphoric acid residue. There are four different nucleotide units in DNA: adenine ("A"), guanine ("G"), cytosine ("C") and thymine ("T").

As explained in *In re Deuel*:

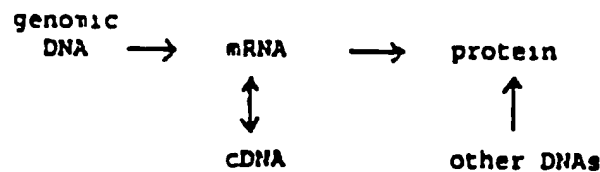
A sequential grouping of three such nucleotides (a "codon") codes for one amino acid. A DNA's sequence of codons thus determines the sequence of amino acids assembled during protein synthesis. Since there are 64 possible codons, but only 20 natural amino acids, most amino acids are coded for by more than one codon. This is referred to as the "redundancy" or "degeneracy" of the genetic code.

DNA functions as a blueprint of an organism's genetic information. It is the major component of genes, which are located on chromosomes in the cell nucleus. Only a small part of chromosomal DNA encodes functional proteins.

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<sup>1</sup>A detailed discussion of the mechanism by which protein C down regulates blood coagulation is provided in Bang et al., U.S. Patent No. 4,775,624. (Ex 1018).

Messenger ribonucleic acid ("mRNA") is a similar molecule that is made or transcribed from DNA as part of the process of protein synthesis. Complementary DNA ("cDNA") is a complementary copy ("clone") of mRNA, made in the laboratory by reverse transcription of mRNA. Like mRNA, cDNA contains only the protein-encoding regions of DNA. Thus, once a cDNA's nucleotide sequence is known, the amino acid sequence of the protein for which it codes may be predicted using the genetic code relationship between codons and amino acids. The reverse is not true, however, due to the degeneracy of the code. Many other DNAs may code for a particular protein. The functional relationships between DNA, mRNA, cDNA, and a protein may conveniently be expressed as follows:



*In re Deuel*, 51 F.3d 1552, 1554, 34 USPQ2d 1210, 1211 (Fed. Cir. 1995).

### III. Findings of Fact

#### 1. Real Parties in Interest

##### a. Junior Party

F1. University of Washington ("UW") is the owner of the entire right, title and interest in the involved U.S. Patent No. 5,302,529 ("529"). Zymogenetics, Inc. is the exclusive licensee of the '529 patent. (Paper No. 11, Notice as to Real Parties In Interest, p. 2).

b. Senior Party

F2. Eli Lilly & Co. ("Lilly") is the real party in interest in the involved U.S. Reissue Patent Application 09/185,663. (Paper No. 5, Eli Lilly & Co. Identification of Real Party in Interest, p. 2).

2. Accorded Priority Benefit

a. Junior Party

F3. UW's involved U.S. Patent No. 5,302,529 issued on April 12, 1994, based upon U.S. Application No. 07/512,961, filed April 23, 1990. Solely for the purposes of priority, UW '529 has been accorded benefit of the filing date of:

U.S. Patent No. 4,968,626, issued November 6, 1990, based upon U.S. Application 06/766,109, filed August 15, 1985.

(Notice Declaring Interference, Paper No. 1, p. 3).

b. Senior Party

F4. Lilly's involved '663 reissue application is based upon U.S. Patent No. 4,775,624, which issued on October 4, 1988 from U.S. Application 06/699,967, filed February 8, 1985. (Notice Declaring Interference, Paper No. 1, p. 3).

3. The Count and Claim Correspondence

F5. Count 1, the sole count in the interference, is claim 3 of UW's U.S. Patent No. 5,302,529.

UW '529 claim 3 reads as follows:



3. The plasmid or transfer vector of claim 1, comprising the cDNA sequence of FIG. 3, from bp 127 to bp 1383.

F6. The claims of the parties are as follows:

UW: 1-4  
Lilly: 1-82 and 84-90

The claims of the parties that have been designated as corresponding to Count 1 are:

UW: 3  
Lilly: 1-82 and 84-90

The claims of the parties that were *not* designated as corresponding to Count 1 are:

UW: 1, 2 and 4  
Lilly: None

(Notice Declaring Interference, Paper No. 1, p. 4).

4. Relevant Facts Admitted By Lilly

a. Differences between the cDNA Sequence of UW Claim 3 and Lilly's Claimed Sequences

Lilly has admitted, among other things, the following material facts presented by UW.

F7. The human protein C cDNA sequence of UW claim 3, from bp 127 to bp 1383 of Foster's Fig. 3, encodes a protein of 419 amino acids, which is a precursor of protein C.

(UW Preliminary Motion 1, Paper No. 17, p. 2, ¶4; Lilly Opposition 1, Paper No. 27, p. 2, ¶4, admitting first sentence of UW fact 4.)

F8. Comparing the sequence of UW Fig. 3, bp 127 to bp 1383, with the pertinent portions of the cDNA sequence of Lilly claim 1, two nucleotide differences are revealed in the coding region:

- 1) UW Fig. 3, nucleotide 423 (third position of codon 99) is thymine ("T"), whereas Lilly's is guanine ("G").
- 2). UW Fig. 3, nucleotide 768, (third position of codon 214) is cytosine ("C"), whereas Lilly's is thymine ("T").

(Paper No. 17, p. 3, ¶6; Paper No. 27, p. 3, admitting UW facts 6-16.) Both Lilly and UW's cDNA sequences are said to encode for human protein C. (Paper No. 27, additional facts ¶¶4, 6 and 7).

F9. The nucleotide variations between UW's Fig. 3 cDNA sequence and the sequence of Lilly claim 1 may be a DNA polymorphism. A polymorphism is defined as one of two different but normal nucleotide sequences existing at a particular site in DNA. The polymorphism may exist in the same individual, e.g., a heterozygous individual or among different individuals, and may encode the same or a different amino acid sequence. (Paper No. 17, pages 2-3, ¶7; Paper No. 27, p. 3, admitting UW facts 6-16.)

F10. According to several of Lilly's named inventors the variations between Lilly's sequence and UW's "may represent a true genetic variant." (Paper No. 17, page 4, ¶8;

Paper No. 27, p. 3, admitting UW facts 6-16.)

F11. In seeking to provoke an interference with UW's '529 patent, Lilly represented to the reissue application examiner that:

. . . it is very likely that the actual Foster [UW] sequence is identical to the corresponding Bang [Lilly] sequence. Indeed, the sequence deposited by Foster in GenBank is **identical** to the corresponding sequence in claim 1 of the Bang application.

Lilly also informed the examiner that:

*The Differences Between the Bang and Foster Sequences are Probably Foster Mistakes*

As the Patent Office has recently recognized, it is well known that sequencing errors are a common problem in molecular biology. [omitted footnote] Evidence supporting the conclusion that the differences between the Bang and Foster sequences are due to sequencing errors by Foster may be found within the Foster patents themselves: the protein C DNA sequences shown in Figure 2 of Foster contains only one of the base differences: that at position 99. Further evidence may be found in the publications of Foster. Specifically, Foster published articles in the *Proceedings of the National Academy of Sciences* that showed DNA sequences matching both Patent Figure 3 (two base differences) and Figure 2 (one base difference). [omitted footnote] Later, Foster made a deposit of their protein C DNA sequence in GenBank; this deposited sequence is **identical** to the sequence of the Bang application.

\* \* \*

Applicants submit that this evidence, when viewed as a whole, clearly supports the conclusion that the two nucleotide differences in the Foster

sequence are due to sequencing errors, and not due to true differences in cDNA sequence.

(Paper No. 17, pages 6-8, ¶13, bold emphasis added; Paper No. 27, p. 3, admitting UW facts 6-16.)

F12. GenBank is a publicly accessible database of nucleic acid sequences.

According to a review article published in 1985, it was GenBank's practice during the 1980's to gather nucleic acid sequences for their database from published scientific literature. (Paper No. 17, p. 8, ¶14; Paper No. 27, p. 3, admitting UW facts 6-16.)

F13. Lilly advised the reissue application examiner that Lilly's sequence was deposited with GenBank under Accession Number X02750. Specifically, Lilly informed the examiner that there is "absolute similarity" between the sequence in Lilly's '663 reissue application and the GenBank X02750 sequence. (Paper No. 17, p. 8, ¶16; Paper No. 27, p. 3, admitting UW facts 6-16.)(Paper No. 17, p. 8, ¶16; Paper No. 27, p. 3, admitting UW facts 6-16.)

F14. Lilly informed the reissue application examiner that GenBank Sequence NM\_000312 was UW's protein C DNA sequence. (Paper No. 17, p. 9, ¶17; Paper No. 27, p. 3, fact 17, stating that Lilly had a good faith belief that its statements regarding the origins of UW's sequences were true and if Lilly was in error, the error was inadvertent.)

F15. Lilly's reissue prosecution statements that Foster deposited the NM\_0003212 are **mistaken**. The record demonstrates that the NM\_0003212 sequence was derived from Lilly's X02750 sequence. (Paper No. 17, p. 10, ¶20; Paper No. 27, p. 3, admitting UW facts 18-21).

b. Coding Sequence Unpredictability

F16. Even if one predicted the existence of at least one DNA polymorphism in a gene, one could not predict where in the coding sequence the difference(s) would occur, how many differences would occur, or what the differences would be. As such, provided with the coding sequence of a single gene, one of ordinary skill in the art could not predict with accuracy the number or location of DNA differences between the genes of different people encoding the same protein. (Paper No. 17, p. 5, ¶10; Paper No. 27, p. 3, admitting UW facts 6-16.)

F17. The two codon differences between UW's claim 3 sequence and Lilly's claim 1 sequence could not have been predicted in advance based on knowledge of either Lilly's nucleotide sequence or Lilly's amino acid sequences. (Paper No. 17, p. 5, ¶11; Paper No. 27, p. 3, admitting UW facts 6-16.)

F18. One of ordinary skill in the art could not have predicted the particular DNA sequence of UW claim 3 based on the amino acid sequence of human protein C light chain, such as that recited in Lilly claim 81, or a particular DNA encoding that amino acid sequence, such as that provided in Lilly claim 82. (Paper No. 17, p. 11, ¶21; Paper No. 27, p. 3, admitting UW facts 18-21).

IV. Opinion

An Administrative Patent Judge ("APJ") declared this interference based, in part, on statements made during the examination of Lilly's reissue application. UW claim 3 is directed to a plasmid or transfer vector comprising a string of base pairs identified in the cDNA sequence of *UW Figure 3*. During the prosecution of Lilly's reissue application, Lilly represented to the examiner that Foster ("UW") had deposited a nucleotide sequence encoding protein C that was **identical** to the corresponding sequence of Lilly's claim 1. (UW Preliminary Motion 1, Paper No. 17, pages 6-8, ¶13, Lilly Opposition 1, Paper No. 27, p. 3, admitted facts 6-16). According to Lilly:

Applicants submit that this evidence, when viewed as a whole, clearly supports a conclusion that the two nucleotide differences in the Foster sequence [*UW Figure 3*] are due to sequencing errors, and not due to true differences in cDNA sequence.

*Id.*

When the interference was declared, the Office was unaware that the purported "Foster sequence," Accession No. NM\_00312 was **Lilly's own sequence**. (Paper No. 17, p. 9, ¶¶17, 20; Paper No. 27, p. 3, Lilly stated that it had a good faith belief that its statements were true and that any error was "inadvertent."). In light of the evidence provided by UW, we find that Lilly's statements regarding the origin of the deposited sequence were incorrect and that the claimed UW species and Lilly species are apparently genetic variants. (See, Paper No. 17, p. 4, ¶8, Paper No. 27, p. 3, admitting facts 6-16).

UW has filed a preliminary motion seeking a judgment of no interference-in-fact based on the differences between the sequence of UW claim 3 and the sequences recited in Lilly's claims. (UW Preliminary Motion 1, Paper No. 17, p. 1). In response to UW's motion, Lilly filed a preliminary motion requesting that the interfering subject matter be redefined to have UW claim 1 designated as corresponding to Count 1. (Lilly Preliminary Motion 1, Paper No. 27, p. 1).<sup>2</sup>

1. What is Required for a Determination of "No Interference-In-Fact"

Both UW and Lilly agree that there is an interference-in-fact when two parties are claiming the same patentable subject matter. The parties, however, disagree as to the test for determining whether the parties claims define the same patentable subject matter.

While 35 U.S.C. § 135(a) sets forth the requirements for declaring an interference, the statute fails to explicitly state the requirements for determining whether there is no interference-in-fact once an interference has been declared. To aid us in our understanding, we look to the United States Patent & Trademark Office's ("USPTO") rules regarding no interference-in-fact. Yet, as the comments to the rules specifically state that USPTO would continue to follow the decisions rendered in Case

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<sup>2</sup> Rule 633(i) allows a party to respond to a motion for no interference in fact by filing, among other things, a motion under Rule 633(c) to redefine the interfering subject matter.

*v. CPC International, Inc.*,<sup>3</sup> *Aelony v. Arni*,<sup>4</sup> and *Nitz v. Ehrenreich*,<sup>5</sup> we review these decisions prior to our review of the USPTO rules. Notice of Final Rules, 49 Fed. Reg. 48416, 48,421 (Dec. 12, 1984).

A. The Opinions of the Federal Circuit and the Court of Customs and Patent Appeals ("CCPA")

1. *Nitz v. Ehrenreich*

*Nitz* involved an appeal from the Board of Patent Interferences<sup>6</sup> awarding priority of invention to Ehrenreich. Specifically, the Board awarded priority of invention as to two counts, counts 1 and 2, to Ehrenreich. Nitz appealed the decision arguing, among other things, that there was no interference-in-fact as to either count.

The interference was provoked when senior party Ehrenreich copied, in modified form, claims 3 and 13 of Nitz's U.S. Patent No. 3,552,533. The subject matter of the two copied claims involved carbonized articles having a modifying agent to increase the coefficient of friction of carbon. Of note, count 1 required up to about 48 percent by weight of a friction modifier and count 2 required carbonized layers of filamentary materials.

During the Board proceeding, Nitz argued that the counts did not define common

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<sup>3</sup>730 F.2d 745, 221 USPQ 196 (Fed. Cir. 1984).

<sup>4</sup>547 F.2d 566, 192 USPQ 486 (CCPA 1977).

<sup>5</sup>537 F.2d 539, 190 USPQ 413 (CCPA 1976).

<sup>6</sup>The decision in *Nitz* occurred prior to the merger of the Board of Interferences with the Board of Patent Appeals.



subject matter that was claimed by both parties. In reviewing Nitz's arguments with respect to count 1, the Board recommended to the Commissioner that the interference be dissolved. Specifically, the Board viewed Nitz's limitation of up to 12 weight percent of a friction modifier as defining a patentably distinct invention from that of count 1, which required up to about 48 weight percent of the friction modifier. The Commissioner, however, disapproved of the recommendation as the Commissioner was of the opinion that the amount of the modifier was not a critical limitation and that there was no basis for Nitz and Ehrenreich's claims to exist in separate patents. As to count 2, the Board determined that the count's failure to recite the term "woundup," as found in Nitz's claimed carbonized layers, was not a patentable distinction.

Additionally, Nitz raised the issue of Ehrenreich's "right to make count 1." As to this issue, the Board determined that Ehrenreich's disclosure was sufficient to support the limitations of the count. Having decided the issues of no interference-in-fact and right to make the counts, the Board awarded priority on both counts to Ehrenreich. Nitz appealed.

In reviewing the question of interference-in-fact and the court's jurisdiction to consider that issue, the CCPA stated:

The existence of common subject matter defined by the interference count is a prerequisite for an award of priority, i.e., the existence or nonexistence of interfering subject matter goes to the very foundation on which an interference rests. Determination of the presence or absence of interfering subject matter is "logically related" to the jurisdiction-conferring issue of priority because that determination necessarily precedes a priority award.

As to the question of no interference-in-fact, the CCPA compared the disclosure and claims of Nitz with the count and the disclosure of Ehrenreich. According to the CCPA:

In the case before us the materiality of the questioned limitation and its variation must be determined in a two-step process wherein the first inquiry is [1] whether the variation changes a material aspect of the patentee's invention (here, whether the maximum amount of friction modifier of "up to 12 percent by weight" is a material limitation) and, if that inquiry be decided in the affirmative, the second inquiry is [2] whether the variation is itself a material variation (here, whether "up to 48% by weight" results in the counts being drawn to a different invention).

*Id.* at 544, 190 USPQ at 417.

Conducting the two-step inquiry, the CCPA focused on Nitz's description that at least 80 weight percent carbon was a critical feature of the invention and the limitation that the modifier was present in an amount "up to 12% by weight." Furthermore, the CCPA focused on Ehrenreich's disclosure of using up to 48% by weight modifier, which would allow for a maximum of 52% by weight carbon. *Id.* at 544, 190 USPQ at 417-18.

The CCPA determined that Nitz's claim recitation of "up to 12% by weight" of a modifier was a material limitation due to the critical nature of having at least 80% carbon. The CCPA then determined that the count language "up to about 48% by weight" of the modifier was a material variation from Nitz's claimed invention. As such, the CCPA concluded that no interference-in-fact existed with respect to count 1. *Id.* at 545, 190 USPQ at 418.

As to count 2, the only issue on appeal was the materiality of Nitz's recitation that the carbonized layers of filamentary materials were "woundup" layers. The CCPA, however, determined that the structure of woundup layers was known in the prior art

and that the limitation was not necessary for the patentability of Nitz's claim. As such, the CCPA determined that Nitz's "woundup" limitation was not a material limitation of Nitz's claim and that an interference-in-fact existed with respect to count 2.

*Nitz* is consistent with the principle that there is no interference-in-fact when two parties are claiming "materially" different inventions. Further, *Nitz* is consistent with the principle that, for purposes of no interference-in-fact, claims of different scope can be separate patentable inventions even where one party's claim is literally encompassed by a second party's claim. Specifically, the CCPA found that Nitz's claimed "up to 12% by weight" modifier was a materially different invention from Ehrenreich's claimed "up to 48% by weight" modifier even though Nitz's claimed amount of modifier was literally encompassed by Ehrenreich's claimed amount of modifier.

## 2. *Aelony v. Arni*

*Aelony* concerned an appeal from a decision of the Board awarding priority of invention to Arni, the senior party. The subject matter of the interference was a method for purifying malononitrile. In particular, both parties treated an impure malononitrile with a conjugated diene in a Diels-Alder reaction to aid in the removal of impurities. Of note, *Aelony* taught the use of cyclopentadiene, a conjugated diene. In contrast, Arni did not specifically describe or claim cyclopentadiene as a suitable Diels-Alder reaction component for the removal of impurities. Rather, Arni specifically described eight other materials having conjugated double bonds as suitable for undergoing a Diels-Alder reaction for the removal of impurities. *Aelony v. Arni*, 547 F.2d 566, 567, 192 USPQ

486, 487 (CCPA 1977).

Before the Board, neither Aelony nor Arni took testimony. Rather, Aelony argued that there was no interference-in-fact between the parties. Specifically, Aelony argued that, for the purification method in dispute, cyclopentadiene was patentably distinct from the eight materials described by Arni. *Id.* at 568, 192 USPQ at 488. The Board did not agree. According to the Board, both parties carried out substantially the same process. Moreover, the Board found that Aelony's patentable distinctiveness argument was unsupported by the evidence. As such, the Board rejected Aelony's no interference-in-fact argument and awarded priority to senior party Arni. *Id.* at 568, 192 USPQ at 488.

In reviewing the merits of Aelony's appeal, the CCPA specifically rejected Aelony's argument that there was no interference-in-fact. The CCPA agreed with the Board "that the test of interference-in-fact is *not* whether two sets of claims overlap, but whether they are patentably distinct from **each other**." *Id.* at 570, 192 USPQ at 490 (bold emphasis added). According to the CCPA, the law contemplates that "where different inventive entities are concerned – that only one patent should issue for inventions which are either identical to or not patentably distinct from **each other**." *Id.* (bold emphasis added). The CCPA went on to state that "[m]oreover, we believe that there is ample precedent from this court for framing the test of interference in fact in terms of whether two sets of claims are patentably distinct from **each other**." *Id.* (bold emphasis added).

On the facts presented, the CCPA determined that "**both parties are claiming the same inventive concept**" and rejected Aelony's argument that there was no

interference-in-fact. *Id.* (bold emphasis added). In particular, the CCPA noted that both parties carried out the same process in which a conjugated diene material reacted with impurities according to the Diels-Alder reaction. Further, there was no dispute that the cyclopentadiene of Aelony and the eight conjugated dienes of Arni were all common Diels-Alder dienes. *Id.*

The decision in *Aelony* denied a motion for no interference-in-fact where two parties were claiming patentably indistinct inventions. Specifically, in deciding the question of no interference-in-fact, the CCPA focused its attention on whether or not the parties claims were patentably distinct from *each other*. Where the claims of the parties are not patentably distinct from each other, the parties are claiming the same inventive concept and it is understood that only one patent should issue.

### 3. *Case v. CPC International, Inc.*

Case involved an appeal from a decision of a district court in a civil action under 35 USC §146 upholding the award of priority to CPC International, Inc., ("CPC") in an interference proceeding in the USPTO. The subject matter in the interference was directed to polyether polyols that consisted essentially of oxyalkylated polyalcohols and oxyalkylated polysaccharides. *Case v. CPC Int'l, Inc.*, 730 F.2d 745, 747, 221 USPQ 196, 198 (Fed. Cir. 1984).

The interference was provoked by CPC. To provoke the interference, CPC copied Case's patented claims. Of note, Case's patented claims specified that an oxyalkylated polyalcohol was present in an amount of 10 to 95% by weight and that an

oxyalkylated polysaccharide was employed in an amount of 5 to 95% by weight. During examination, CPC's claims were rejected as lacking sufficient written descriptive support under 35 U.S.C. § 112, 1st paragraph, for the copied weight limitations. The examiner, however, advised CPC to submit claims directed to "a polyether polyol which is the reaction product of starch and the various disclosed derivatives thereof with glycerin and propylene oxide." *Id.* In response to the examiner's rejection of the copied claims, CPC canceled the copied claims and submitted new claims that complied with the examiner's suggestion. *Id.* The newly added CPC claims, however, did not recite a particular weight limitation for the two oxyalkylated components. Moreover, when the interference was declared, the counts did not recite the weight limitations found in Case's patented claims.

Case presented numerous arguments challenging both the district court and the Board's award of priority to CPC. Of interest, Case argued that no interference-in-fact existed between Case's claims and CPC's. According to Case, the question of no interference-in-fact turned on whether or not the weight limitations present in Case's claims, but not CPC's claims, were material. The Federal Circuit agreed with this analysis.<sup>7</sup> *Id.* at 750, 221 USPQ at 200.

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<sup>7</sup>Specifically, the Federal Circuit stated:

Case challenges the declaration of the interference on the ground that no interference in fact exists. Relying on *Nitz v. Ehrenreich*, 537 F.2d 539, 190 USPQ 413 (CCPA 1976), Case argues that the question of interference in fact turns on whether or not the weight limitations present in the claims of Case's patent but omitted from the counts are material. We agree with this analysis but we see no departure by the board or the court in stating the law or applying it to the facts of this case.

According to the Federal Circuit, the question of materiality of the omitted limitations was one of fact. *Id.* The Court noted that both the district court and the Board had determined that the omitted weight limitations were not material as the range of proportions was quite broad and that Case's prosecution history demonstrated that the omitted limitations were not pertinent to patentability.

Additionally, Case argued that there was no interference-in-fact as the counts were unpatentable. Having reviewed Case's arguments, the Federal Circuit stated that:

***No interference in fact means that there is no interfering subject matter, that Case's patent is no impediment to granting CPC the claims of its application.*** It was Case's burden to prove that CPC claims a different invention from his own. Case cannot carry that burden with argument that the counts are unpatentable.

*Id.* (emphasis added). The Federal Circuit also stated that "[i]n sum, since the Case patent and the CPC application contain interfering subject matter, an interference proceeding was appropriate." *Id.* at 752, 221 USPQ at 202. The Court then went on to uphold the decision awarding priority of invention to CPC based upon its earlier application. *Id.*

As apparent from the decision in Case, the question of no interference-in-fact turns on whether or not the parties claims are "materially" different. The question of "material" differences being one of fact. Further, Case specifies that no interference-in-fact exists where one party's patent does not impede the grant of another party's claims.

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*Id.*

4. Summary of the CCPA and Federal Circuit Opinions on the Question of No Interference-in-Fact

An interference in fact involves interfering subject matter. As shown by the above decisions, there is no interfering subject matter, and thus, no interference-in-fact when the parties are claiming different patentable inventions. For example, there is no interference-in-fact when it is demonstrated that a party's claims are no impediment to the granting of an opponents claims. *Case*, 730 F.2d at 750, 221 USPQ at 200.

The cases analyzed above, *Nitz*, *Aelony* and *Case* and our interpretations thereof are all consistent with the no interference-in-fact decisions in *Almasi v. Strauss*, 589 F.2d 523, 200 USPQ 511 (CCPA 1979), and *Brailsford v. Lavet*, 318 F.2d 942, 138 USPQ 28 (CCPA 1963) as well as the interference-in-fact decision in *McCabe v. Cramblet*, 65 F.2d 459, 18 USPQ 71 (CCPA 1933).

B. The USPTO Rules and the Comments to the Rules Provide that No Interference-in-Fact Exists for Patentably Distinct Inventions

The interference rules were revised in 1984 to implement the interference provisions of the Patent Law Amendments Act of 1984 (Public Law 98-622). Notice of Final Rule, Patent Interference Proceedings, 49 Fed. Reg. 48416 (Dec. 12, 1984). As part of the rule revision, the Commissioner (now Director) promulgated several rules regarding the existence of an interference-in-fact. For example, the Commissioner promulgated 37 CFR Section 1.601(j)(definition of an interference-in-fact), Section 1.601(n)(definition of same and separate patentable inventions) and Section 1.633(b),



which authorized parties to file preliminary motions for judgment on the ground that there is no interference-in-fact.

In their present form, Rules 601(j), 601(n) and 633(b) read as follows:

Rule 601(j) An *interference-in-fact* exists when at least one claim of a party that is designated to correspond to a count and at least one claim of an opponent that is designated to correspond to the count define the same patentable invention.

Rule 601(n) Invention "A" is the *same patentable invention* as an invention "B" when invention "A" is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A". Invention "A" is a *separate patentable invention* with respect to invention "B" when invention "A" is new (35 U.S.C. 102) and non-obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A".

Rule 633(b) A motion for judgment on the ground that there is no interference-in-fact. A motion under this paragraph is proper only if the interference involves a design application or patent or a plant application or patent or no claim of a party which corresponds to a count is identical to any claim of an opponent which corresponds to that count. See §§1.637(a). When claims of different parties are presented in "means plus function" format, it may be possible for the claims of the different parties not to define the same patentable invention even though the claims contain the same literal wording.

Rules 601(j) and (n): 49 FR 48416, Dec. 12, 1984, effective Feb. 11, 1985; 50 FR 23123, May 31, 1985; revised, 60 FR 14488, Mar. 17, 1995; Rule 633(b): 49 FR 48416, Dec. 12, 1984, added effective Feb. 11, 1985; 50 FR 23124, May 31, 1985; revised, 60 FR 14488, Mar. 17, 1995, effective Apr. 21, 1995.

While the rules explicitly define when an *interference-in-fact* exists, the rules do not explicitly define "no" interference-in-fact. The comments to the rules, however, provide that the USPTO will continue to follow the decisions rendered in *Nitz*, *Aelony*

and Case. Notice of Final Rules, 49 Fed. Reg. 48416, 48421 (Dec. 12, 1984). As provided above, these three decisions demonstrate that the test for no interference-in-fact is grounded in patentable distinctness. *Nitz*, 537 F.2d at 545, 190 USPQ at 418; *Aelony*, 547 F.2d at 570, 192 USPQ at 490; *Case*, 730 F.2d at 750, 221 USPQ at 200. As such, a party may demonstrate that no interference-in-fact exists between two parties by proving that a first party's claim(s) are patentably distinct from the second party's claim(s).

The test for patentable distinctness is set forth in Rule 601(n), which states that an invention "A" is a separately patentable invention, i.e. patentably distinct, with respect to invention "B" when invention "A" is novel and non-obvious in view of invention "B" assuming invention "B" is prior art with respect to invention "A". For example, party A's claims are patentably distinct, i.e., separately patentable, when the party A's claims are no impediment to the granting of the opponents claims. See, e.g., *Nitz*, 537 F.2d at 544-45, 190 USPQ at 417-18 (No interference-in-fact where "up to 48%" modifier did not interfere with "up to 12%" modifier); *Case*, 730 F.2d at 750, 221 USPQ at 200 ("No interference in fact means that there is no interfering subject matter, that Case's patent is no impediment to granting CPC the claims of its application.").

C. Lilly's Species Anticipates Dominating Genus Theory of Interference-in-Fact Lacks Merit

Lilly argues that for an interference in fact, the interference rules and comments require nothing more than a "species anticipates dominating genus" determination.

Thus, according to Lilly, its claimed species is the "same patentable invention" as UW's claimed genus based on the fact that its species would anticipate UW's genus.

Lilly states that the comments specifically inform the public that the test under Rule 601(n) for determining the "same" patentable invention could not be applied two ways, i.e. a party need only demonstrate "one-way" anticipation or obviousness for an interference-in-fact. Specifically, Lilly has argued that:

The regulations of the PTO, 37 CFR §1.601(n), having the force and effect of law, require nothing more than the "species anticipates dominating genus" determination to establish the existence of an interference-in-fact. Indeed, the official commentary issued by the PTO at the time the rules were adopted made clear that the test for the "same patentable invention" under 37 CFR §1.601(n) could not be applied two ways. 49 FR 48416 at 48434 (Dec. 12, 1984). ***As stated by the PTO in the administrative history for the regulations, the "same patentable invention" [test] . . . under §1.601(n) . . . [is] not intended to be 'applied in a mutuality sense.'*** [Footnote omitted].

(Lilly Preliminary Motion 1, Paper No. 22, p. 5, emphasis added). Additionally, responding to comments from UW, Lilly stated:

In response to a specific question posed by one commentator in 1984 asking whether the PTO's proposed Rule 1.601(n) would involve a one-way or two-way patentability determination, the Office responded in unequivocal terms that a one-way test would be applied. Notice of Final Rules, 49 Fed. Reg. 48,416, 48,433 (1984). Six years later this rule was restated by the Board in *Chiong v. Roland*, 17 U.S.P.Q.2d 1541, 1544 (Bd. Pat. App. & Int. 1990) ("As pointed out in the Notice, supra at 48433, ***the standard of patentability will not be applied on a 'mutual basis.'***")

(Lilly Reply 1, Paper No. 30, pages 8-9, emphasis added). This panel has reviewed the comments to the rules and finds no merit in Lilly's "species anticipates dominating genus" test.

Lilly has relied upon two specific comments to the rules. The comments may be

found at pages 48,433-48,434 of the Notice of Final Rules, 49 Fed. Reg. 48,416 (Dec. 12, 1984). Provided below are the full paragraphs ((1) & (2)) from which Lilly's quoted material is derived:

- (1) With respect to paragraph (1) of the comment, the standard of patentability will not be applied "on a mutual basis." **Thus, if a species is patentable over a genus, the species is a "separate patentable invention" from the genus.** Compare *In re Taub*, 348 F.2d 556, 146 USPQ 384 (CCPA 1965) (fluorine species might be patentable over genus of Markush group of hydrogen and halogen). A first count to a genus and a second count to a species which is patentable over the genus may properly appear in an interference. See e.g., Example 4. The comment suggests that if "such mutuality is not applied \* \* \* then a number of irreconcilable anomalies \* \* \* will be manifest." The urged "irreconcilable anomalies" are not readily apparent to the PTO.

(Fed. Reg., p. 48433, underline emphasis added denotes Lilly's cited commentary, bold emphasis added to highlight application of Rule 601(n) for genus/species situations).

- (2) Analysis of Commentator's Example A. Example A does not describe any practice under these rules, because "same patentable invention" and "separate patentable invention" under § 1.601(n) are not intended to be "applied in a mutuality sense." **Where a first count is to a genus and a second count is to a species within the scope of the genus, there may be two counts if the species is separately patentable from the genus.** The species is "invention A" referred to in § 1.601(n); the genus is "invention B" referred to in § 1.601(n).

(Fed. Reg., p. 48434, underline emphasis added denotes Lilly's cited commentary, bold emphasis added to highlight application of Rule 601(n) for genus/species situations).<sup>8</sup>

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<sup>8</sup>While not specifically mentioned by Lilly, Lilly's relied upon comments were written in response to questions concerning whether or not the standard of patentability would be applied on a mutual basis in determining whether to add an additional count. Each count, of course, must be directed to a separate patentable invention. 37 CFR §1.601(f). In other words, the comments responded to a question of whether the USPTO would require that Invention A be separately patentable from Invention B considered as prior art **and** Invention B be separately patentable from Invention A

The comments to the rules regarding the test for "same or separate patentable inventions" are highly relevant and material to the issues raised in this interference as they inform the public that a *genus* and a patentably distinct *species* are separate patentable inventions. If the rule were only applied in the manner suggested by Lilly, i.e., nothing more than species anticipates dominating genus, then the comments to the rule that a species that is patentable over a genus is a "separate patentable invention" from the genus would make no sense. Specifically, Lilly's argument would have us determine that the species and dominating genus defined both the same patentable invention and, at the same time, a separate patentable invention. Consistent with the precedential Federal Circuit and CCPA opinions mentioned above, the comments to rules explicitly provide that a patentably distinct species and a dominating genus are ***separately patentable*** inventions.

2. Lilly and UW's Corresponding Claims Are Separate Patentable Inventions  
As UW's Corresponding Claims Do Not Impede the Grant of Lilly's  
Corresponding Claims

The test for no interference-in-fact is whether or not the parties are claiming separately patentable inventions. In applying this test, we begin with a comparison of the parties' corresponding claims as there exists a rebuttable presumption that each

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considered as prior art), in order for an interference to have both a species count and a genus count. The answer to this was no. Notice of Final Rules, 49 Fed. Reg. 48,416, 48432-434 (Dec. 12, 1984). Note, the test for no interference-in-fact and the addition of new count is essentially the same, i.e., patentable distinctness. See, e.g., *Hester v. Allgeier*, 646 F.2d 513, 521, 209 USPQ 370, 378 (CCPA 1982).

claim designated to correspond to a count defines the same patentable invention as all other claims designated to correspond to the count. See, e.g., *Orikasa v. Oonishi*, 10 USPQ2d 1996, 2004 (Comm'r Pat. & Trademark 1989).

Count 1 is the sole count in interference. As declared, UW claim 3 and Lilly claims 1-82 and 84-90 correspond to Count 1. Additionally, Lilly has requested that UW claim 1 be designated as corresponding to Count 1. For purposes of determining if there is no interference-in-fact between the parties, we will assume that Lilly is correct in stating that UW claim 1 corresponds to Count 1. Accordingly, we compare UW claims 1 and 3 with Lilly's corresponding claims to determine whether the parties are claiming separately patentable inventions.

A. Anticipation and Obviousness

A prima facie case of obviousness is established when the teachings of the prior art would have suggested the claimed subject matter to a person of ordinary skill in the art with a reasonable likelihood of success of achieving the suggested invention. *In re Dow Chem.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). Any motivation or suggestion to modify the prior art references must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed Cir. 1995); *In re Gorman*, 933 F.2d 982, 986-87, 18 USPQ2d 1885, 1888, (Fed. Cir. 1991).

A claim to a specific cDNA is not made obvious by mere knowledge of a desired protein sequence and methods for generating the various cDNA that have the potential

to encode that protein. *Cf., Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1567, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997) ("We had previously held that a claim to a specific DNA is not made obvious by mere knowledge of a desired protein sequence and methods for generating the DNA that encodes that protein."); *In re Deuel*, 51 F.3d 1552, 1558, 34 USPQ2d 1210, 1215 (1995) ("A prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein."); *In re Bell*, 991 F.2d 781, 787, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993) ("It may be true that, knowing the structure of the protein, one can use the genetic code to hypothesize possible structures for the corresponding gene and that one thus has the potential for obtaining that gene. . . . Therefore, given the nearly infinite number of possibilities suggested by the prior art, and the failure of the cited prior art to suggest which of those possibilities is the human sequence, the claimed sequences would not have been obvious.").

Anticipation is the epitome of obviousness. *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983) (citing *In re Fracalossi*, 681 F.2d 792, 215 USPQ 569 (CCPA 1982)). Anticipation is established only if each and every element of a properly construed claim is found, either expressly or inherently described, in a prior art reference. *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1624-1625 (Fed. Cir. 1996).

B. UW Claim 3 is Patentably Distinct from Lilly's Corresponding Claims

UW claim 3 is directed to a plasmid or transfer vector that comprises the cDNA sequence depicted in UW Figure 3, from base pair 127 to base pair 1383. Lilly claim 1 corresponds to Count 1 and requires a constructed DNA compound that encodes a polypeptide with human protein C activity wherein the coding strand comprises several distinct cDNA species. Lilly claims 2-75, 77-80 and 84-88 all depend from Lilly claim 1 or require a DNA compound of Lilly claim 1. Of the remaining Lilly corresponding claims, Lilly claim 76 is directed towards several "intermediate" plasmids that lack the protein C cDNA, while Lilly claims 81 and 82 relate to recombinant DNA sequences that comprise the coding sequence for the active light chain of human protein C. Thus, as it is readily apparent that Lilly's intermediate plasmids are patentably distinct from UW claim 3, the proper comparison for patentable distinctness is between the cDNA species of UW claim 3 and the cDNA species recited in Lilly claim 1 and Lilly claims 81 and 82.<sup>9</sup>

The sequence claimed in UW claim 3 is a cDNA sequence having at least 1257 base pairs, i.e., 419 codons (three base pairs to a codon), that encode a protein of 419 amino acids. For such a sequence, the odds of randomly changing a single codon are 1 in 419, changing any two codons at random is 1 in 175,142 ( $419 \times 418$ ), changing any three codons at random is 7,303,214 ( $419 \times 418 \times 417$ ), etcetera. (See generally,

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<sup>9</sup>While Lilly's corresponding claims encompass several distinct species of cDNA, for reasons of convenience we refer to Lilly claims as "species" claims as opposed to "genus" or "subgenus" claims.



Paper No. 17, pages 5-6, ¶ 11).

Comparing the sequence of UW claim 3 (UW Fig. 3, bp 127 to bp 1383) with the pertinent portions of the cDNA sequence of Lilly claim 1, two nucleotide differences are revealed in the coding region:

- 1) UW Fig. 3, nucleotide 423 (third position of codon 99) is thymine ("T"), whereas Lilly's is guanine ("G").
- 2) UW Fig. 3, nucleotide 768, (third position of codon 214) is cytosine ("C"), whereas Lilly's is thymine ("T").

(Paper No. 17, p. 3, ¶6; Paper No. 27, p. 3, admitting UW facts 6-16.). The parties agree that:

The particular differences in the nucleotide sequences that occur between the sequences of Foster [UW] claim 3 and Bang [Lilly] claim 1 within two different codons could not have been predicted in advance based on knowledge of either Bang's nucleotide or amino acid sequences alone.

(Paper No. 17, p. 5, ¶11; Paper No. 27, p. 3, admitting UW facts 6-16.).

When there is a specific, structurally related prior art compound, the question of obviousness is whether the prior art suggested the specific modifications necessary to achieve the claimed compound. *In re Deuel*, 51 F.3d at 1557-58, 34 USPQ2d at 1214. On the record presented, there is insufficient evidence that Lilly's claimed sequence, taken in combination with the prior art, would have suggested the specific modifications to nucleotide 423 and nucleotide 768 such that one skilled in the art would arrive at the cDNA sequence described by UW claim 3. Additionally, there is insufficient evidence that one skilled in the art presented with the amino acid sequence of human protein C would have been guided to form the specific cDNA sequence recited in UW claim 3. *In re Deuel*, 51 F.3d at 1559, 34 USPQ2d at 1215-16 (Due to enormous number of DNA

molecules encoding for the protein, disclosure of amino acid sequence did not render particular DNA molecules encoding the protein obvious). We conclude that Lilly claim 1 and UW claim 3 are patentably distinct as Lilly claim 1 does not render UW claim 3 obvious. Furthermore, Lilly claim 1 does not anticipate UW claim 3 as Lilly claim 1, taken in light of the prior art, fails to teach all the limitations of UW claim 3.

Lilly claims 81 and 82 are directed to the coding sequence for the active light chain of human protein C. Lilly claim 81 does not specifically recite the structure of the coding sequence whereas Lilly claim 82 specifically sets forth the coding strand. The coding strand in Lilly claim 82 contains 465 base pairs, i.e., 155 codons. In contrast, UW claim 3 is directed to the cDNA encoding protein C and contains 1257 base pairs, i.e., 419 codons. The amino acid sequence of human protein C light chain, such as that recited in Lilly claim 81, and a particular DNA encoding that amino acid sequence, such as that provided in Lilly claim 82, do not provide sufficient information for one skilled in the art to predict the particular DNA sequence of UW claim 3. (Paper No. 17, p. 11, ¶21; Paper No. 27, p. 3, admitting UW facts 18-21). As Lilly claims 81 and 82 fail to teach or suggest the cDNA of UW claim 3, we conclude that UW claim 3 is patentably distinct from Lilly claims 81 and 82.

C. Lilly's Corresponding Claims Are Patentably Distinct from UW Claim 1

UW claim 1 is directed to a plasmid or transfer vector that comprises cDNA coding for a human protein C. According to Lilly, there are two possible claim constructions for UW claim 1. (See, Paper No. 30, pages 4-5). First, Lilly contends that

UW claim 1 must be construed as "limited to the specific allelic cDNA sequence disclosed in the UW '529 Patent, as is claim 3 of the UW '529 Patent" and that "claim 1 of the UW '529 Patent is essentially equivalent to claim 3 of the UW '529 Patent." (Paper No. 27, p. 7 and p. 9 and Paper No. 30, p. 4). Alternatively, Lilly argues that it is expected that UW will contend that claim 1 is generic and encompasses not only the cDNA sequence that UW discovered, but also the cDNA sequence discovered by Lilly. (See, Paper No. 27, p. 9). It is not necessary for us to determine whether UW claim 1 is as broad or as narrow as Lilly contends. There is no interference-in-fact under either claim construction. If we construe UW claims 1 and 3 as "essentially equivalent," there is no interference-in-fact as Lilly's corresponding claims do not teach or suggest the cDNA of UW claim 3 and would likewise not teach or suggest an "essentially equivalent" cDNA of UW claim 1. Specifically, Lilly's corresponding claims do not teach or suggest the particular number and location of the polymorphisms in the cDNA of UW claim 3 nor would they teach or suggest a such polymorphisms in a similarly construed claim.

If we construe UW claim 1 to be a generic claim covering any cDNA sequence that encodes human protein C, there is still no interference-in-fact. So construed, UW claim 1 would encompass thousands of possible sequences. Given such a vast number of possible sequences encompassed by a broadly construed UW claim 1, there would need to exist some suggestion or teaching in the prior art that guided one skilled in the art to the specific species claimed by Lilly. See *In re Baird*, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994)(Prior art teaching of "vast number" of possible diphenol

compounds did not teach or suggest the selection of Baird's claimed bisphenol A); *In re Belle*, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993)(DNA sequence would not have been obvious in view of prior art reference that taught a vast number of possibilities but did not teach or suggest why, among all those possibilities, one would seek the claimed sequence). The evidence presented fails to teach or suggest the selection of Lilly's claimed cDNA species from among the vast number of potential sequences that would be encompassed by a broadly construed UW claim 1. As UW claim 1, taken in light of the prior art, does not fairly teach or suggest Lilly's specifically claimed species, Lilly's claimed species are patentably distinct from a broadly construed UW claim 1. As a patentably distinct species is a "separate patentable invention" from its dominating genus, there is no interference in fact between a broadly construed UW claim 1 and Lilly's corresponding claims.

Based on the facts presented, neither UW claim 1 nor UW claim 3 impedes the grant of Lilly's corresponding claims. *Case*, 730 F.2d at 750, 221 USPQ at 200. As UW's allegedly corresponding claims do not impede the issuance of Lilly's corresponding claims, there is no interference-in-fact. UW Preliminary Motion 1 for no interference-in-fact is **granted**.

3. Lilly Did Not Have Authorization to Set Its Own Time Period for Filing Motions to Add or Substitute a Count

Lilly had a full and fair opportunity to file motions responding to UW's motion for no interference-in-fact. Specifically, UW's motion was filed under Rule 633(b). Rule 633(i) permits a party to respond to such a motion by filing a motion to: (i) redefine the

interfering subject matter (633(c)); (ii) substitute a different application (633(d)); or (iii) add a reissue application to the interference (633(h)). As such, Lilly had the opportunity to file a motion to redefine the interfering subject matter by adding or substituting a count or seek to have the claim correspondence changed. See, 37 CFR §§ 1.633(b), (c) and (i). Rather than file a motion to add or substitute a count, Lilly stated that:

If this interference proceeds, further redefinition of the interfering subject matter would be necessary and desirable. For example, some modification of the Count itself will be necessary under 37 C.F.R. § 1.633(c)(1) so that it encompasses the subject matter of the involved Bang reissue claims currently designated as corresponding to the count. Otherwise, Lilly could be improperly denied the opportunity to present its best priority proofs. [Citation omitted]. Such modification of the Count is not necessary to resolve the interference-in-fact issue that is the subject of this special motion period, which merely turns on the "same patentable invention" relationship between the respective claims of the parties designated as corresponding to the Count. If a Preliminary Motion Period is set, Lilly will present an appropriate motion to modify the Count itself to exercise its right to have a count representing its "best proofs." In the same vein, Lilly will move during the Preliminary Motions Period to appropriately further modify the scope of the interference by designating the appropriate claims of the parties as corresponding to the Count.

(Lilly Preliminary Motion 1, Paper No. 22, p. 6, fn. 2).

Under the rules, a preliminary motion under §§ 1.633 (a) through (h) shall be filed within a time period set by an APJ. Moreover, the time for filing motions under § 1.633 (i) is twenty (20) days after service of the initial motion under rule 633(a), (b), (c)(1) or (g), unless otherwise ordered by an APJ. 37 CFR §§ 1.636 (a) and (b).

In this case, an APJ set a specific time period for filing motions for no interference-in-fact or for judgment of unpatentability under 35 U.S.C. § 135(b). (Order, Paper No. 16). The APJ also set a specific time period for filing responsive rule 633(i) and (j) preliminary motions. (Order, Paper No. 16). As noted above, Lilly has chosen to

*sua sponte* set its own schedule for submitting motions to redefine the interfering subject matter.

Lilly's failure to comply with the times set by the APJ undermines the APJ's ability to secure a "just, speedy, and inexpensive" determination of this interference. By failing to timely file its motions to redefine the interfering subject matter, Lilly has avoided the difficult and complex question of what a proper count and claim correspondence would be if this interference were to proceed. Further, if Lilly had timely filed its "necessary and desirable" motions to redefine the interfering subject matter, Lilly's motions may have provided additional evidence regarding the existence of an interference-in-fact or lack thereof. Lilly instead chose a more limited approach and is subject to the consequences of its choices.

4. The Panel Will Not Exercise Its Discretion Under Rule 641 to Review the Patentability of UW Claim 1

Lilly has argued that the issue of UW's written descriptive support for UW claim 1 is presently before the Board. This is not the case. Neither Lilly nor UW has briefed this particular issue. Moreover, as the panel has determined that there is no interference-in-fact between UW and Lilly, no Rule 1.633(a) patentability motions will be accepted from the parties. This is not to say that the panel has determined that UW claim 1 is patentable, but rather it is a recognition that Lilly will not be afforded the opportunity to submit unpatentability motions where there is no interference-in-fact. *Berman v. Housey*, 2002 U.S. App. LEXIS 10256 at \*24 (Fed. Cir. 2002)(Refusal by Board to address issues of priority and patentability once it determined that there is no

interference-in-fact is supported by sound policy considerations).

During the course of an interference, if an APJ become aware of a reason why a claim designated as corresponding to the count may not be patentable, the APJ has the discretion to enter an order notifying the parties of the reasons and set a time for each party to present its views. 37 CFR § 1.641. This interference was declared based, in part, on Lilly's allegations that a nucleotide sequence encoding protein C deposited by UW was identical to that of Lilly's. These allegations proved to be erroneous, albeit inadvertently. Given the circumstances of this interference, the panel chooses not to exercise its discretion under Rule 1.641 and explore the patentability or unpatentability of UW claim 1.

5. Lilly Contingent Miscellaneous Motion 2 is Moot

Lilly filed a motion seeking leave to belatedly file a preliminary statement. (Lilly Contingent Miscellaneous Motion 2, Paper No. 41, p. 1). Lilly's motion is contingent on the determination that there is an interference-in-fact. As we have granted UW Preliminary Motion 1 for no interference-in-fact, Lilly's miscellaneous motion is moot.

6. Additional Comments

Lilly has argued that they have no other remedy in the USPTO. (Paper No. 27, p. 11). According to Lilly, a reexamination of UW's 529 patent is not available as Lilly's '624 patent was cited during the prosecution of UW's patent and UW overcame this rejection by filing a declaration under 37 CFR § 1.131. As such, Lilly concludes that the

issue of Lilly's alleged work under § 102(g) should be resolved in an interference proceeding. Lilly also argues that the failure to recognize an interference-in-fact under the present circumstances leads to the "absurd, inequitable, and unlawful" result that Lilly's practice of its own prior invention may be alleged to infringe UW's claims.

The existence or nonexistence of another remedy within the USPTO is not a basis for continuing an interference where none exists. Should Lilly believe that an actual controversy exists between the UW '529 patent and Lilly's activities, Lilly may file a declaratory judgment action in district court.

#### ORDER

Upon consideration of the motions, it is:

**ORDERED** that UW Preliminary Motion 1 for no interference-in-fact is ***granted***.

**FURTHER ORDERED** that there is no interference-in-fact between claims 1 and 3 of UW, U.S. Patent No. 5,302,529 and claims 1-82 and 84-90 of Lilly, U.S. Application No. 09/185,663.

**FURTHER ORDERED** that Lilly Preliminary Motion 1 to designate an additional patent claim is ***moot***.

**FURTHER ORDERED** that Lilly Contingent Miscellaneous Motion 2 for leave to belatedly file a preliminary motion is ***moot***.

**FURTHER ORDERED** that if there is a settlement agreement, attention is directed to 35 U.S.C. § 135(c) and 37 CFR § 1.661.



**FURTHER ORDERED** that a copy of this final decision shall be placed and given  
a paper number in the file of Foster, U.S. Patent No. 5,302,529 and Bang, U.S.  
Application No. 09/185,663.

  
RICHARD E. SCHAFER  
Administrative Patent Judge

  
RICHARD TORCZON  
Administrative Patent Judge

  
MICHAEL P. TIERNEY  
Administrative Patent Judge

BOARD OF  
PATENT  
APPEALS AND  
INTERFERENCES

INTERFERENCE  
TRIAL SECTION

cc (first-class mail):

Counsel for University of Washington  
(Zymogenetics, Inc., exclusive  
licensee):  
Edward J. Keeling  
Steven W. Parmalee  
TOWNSEND AND TOWNSEND AND  
CREW, LLP  
2 EMBARCADERO CTR FL 8  
SAN FRANCISCO CA 94111-3834  
  
Tel: 415-576-0200  
Fax: 415-576-0300

Counsel for Eli Lilly & Co.:  
Charles E. Lipsey  
Kenneth J. Meyers  
FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.  
1300 I ST NW STE 700  
WASHINGTON DC 20005-3315  
  
Tel: 202-408-4000  
Fax: 202-408-4400

#50

United States Court of Appeals for the Federal Circuit

02-1610  
(Interference No. 104,733)

SOLICITOR

OCT 27 2003

ELI LILLY & CO.,

U.S. PATENT & TRADEMARK OFFICE

Appellant,

v.

BOARD OF REGENTS OF THE UNIVERSITY OF WASHINGTON,

Appellee.

Charles E. Lipsey, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC, argued for appellant. With him on the brief were Kenneth J. Meyers and Deborah Katz. Of counsel on the brief were Brian P. Barrett and Steven P. Caltrider, Eli Lilly and Company, of Indianapolis, Indiana.

William F. Lee, Hale and Dorr LLP, of Boston, Massachusetts, argued for appellee. With him on the brief were Lisa J. Pirozzolo, of Boston, Massachusetts; and James L. Quarles III and Henry N. Wixon, of Washington, DC. Of counsel were Maria L. Maebius and William G. McElwain, of Washington, DC.

John M. Whealan, Solicitor, United States Patent and Trademark Office, of Arlington, Virginia, for amicus United States Patent and Trademark Office. With him on the brief were James A. Toupin, General Counsel; and Stephen Walsh and Henry G. Sawtelle, Associate Solicitors.

Appealed from: United States Patent and Trademark Office  
Board of Patent Appeals and Interferences

10/27

# United States Court of Appeals for the Federal Circuit

02-1610  
(Interference No. 104,733)

ELI LILLY & CO.

SOLICITOR

OCT 27 2003

U.S. PATENT & TRADEMARK OFFICE  
Appellant,

v.

BOARD OF REGENTS OF THE UNIVERSITY OF WASHINGTON,

Appellee.

---

DECIDED: July 3, 2003

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Before MICHEL, LOURIE, and GAJARSA, Circuit Judges.

Opinion for the court filed by Circuit Judge GAJARSA. Circuit Judge LOURIE dissents.  
GAJARSA, Circuit Judge.

This is an appeal from a patent interference proceeding before the United States Patent and Trademark Office ("PTO") Board of Patent Appeals and Interferences ("Board"). The Board granted the Board of Regents of the University of Washington's ("UW's") motion declaring that no interference-in-fact existed on the grounds that the invention of the corresponding claims of U.S. Reissue Application No. 09/185,663 ("the '663 reissue application") to Eli Lilly & Co. ("Lilly") are separately patentable over that of U.S. Patent No. 5,302,529 ("the '529 patent") assigned to UW. Bd. of Regents of the Univ. of Wash. v. Eli Lilly & Co., Patent Interference No. 104,733 (Bd. Pat. App. & Int. June 11, 2002). Because the Director of the PTO's ("Director's") interpretation of 37 C.F.R. § 1.601(n) as establishing a "two-way" test for determining whether two

parties are claiming the "same patentable invention" is neither plainly erroneous nor inconsistent with the regulation, and the Board committed no reversible error in applying the two-way test to determine that the '529 patent and the corresponding claims of the '663 reissue application do not define the same patentable invention, we affirm.

## I. BACKGROUND

On November 4, 1998, Lilly filed the '663 reissue application to surrender its own U.S. Patent No. 4,775,624 ("the '624 patent") and requested an interference between its reissue application and the '529 patent. The Board declared an interference on August 7, 2001 between the '663 reissue application and the '529 patent. The claimed subject matter relates to a complementary deoxyribonucleic acid ("cDNA") sequence that codes for human protein C, which plays an important role in the regulation of blood coagulation and generation of fibrinolytic activity in vivo. Lilly filed new claims 1-82 and 84-90 of the '663 reissue application and requested that only claim 3 of the '529 patent be designated as corresponding to the sole count in the interference: "A plasmid or transfer vector of Foster claim 3 [of the '529 patent]."

Claim 1 of the '529 patent, which is the independent claim from which claim 3 depends, reads:

1. A bacterial plasmid or bacteriophage transfer vector comprising cDNA coding for the amino acid sequence of FIG. 3, starting with alanine, number 1, and ending with proline, number 419, said cDNA sequence coding for human protein C.

'529 patent, col. 6, ll. 48-52.

Claim 3 recites:

3. The plasmid or transfer vector of claim 1, comprising the cDNA sequence of FIG. 3, from bp [base pair] 127 to bp 1383.

Id. at col. 6, ll. 57-59.

UW's '529 patent was a continuation of, and was accorded the benefit of, U.S. Patent No. 4,968,626 (issued Nov. 6, 1990), which was filed on August 15, 1985. Lilly's '663 reissue application was accorded the benefit of the February 8, 1985 filing date of the '624 patent (issued Oct. 4, 1988). Accordingly, in the declaration of interference in which claim 3 of the '529 patent was the interference count, Lilly was made the presumptive senior party.

During the preliminary motions period, UW filed a motion for judgment on the ground that there is no interference-in-fact, explaining that the parties' cDNA molecules have different sequences, i.e., chemical structures. The Board agreed that the evidence established the differences and found that Lilly's claims do not define the same patentable invention as claim 3 of the '529 patent. Thus, the Board granted UW's motion for no interference-in-fact and dismissed the interference.

After failing to instigate an interference with the '529 patent based upon claim 3, Lilly filed a motion to redefine the interfering subject matter by designating claim 1 of the '529 patent as also corresponding to the sole count in the interference. Lilly proposed two alternative constructions of claim 1 of the '529 patent: (1) a narrow construction claiming the specific cDNA sequence recited in Figure 3 of the '529 patent ("species claim construction"), and (2) a broad construction claiming any cDNA sequence that codes for human protein C ("genus claim construction"). Applying a two-way test pursuant to its regulation, 37 C.F.R. § 1.601(n), the Board found that, whether claim 1 of the '529 patent is construed as a genus or as a species, the corresponding claims of the '663 reissue application do not define the "same patentable invention" as

claim 1 of the '529 patent, and determined that there is no interference-in-fact between the corresponding claims of the '663 reissue application and claim 1 of the '529 patent. Accordingly, the Board dismissed as moot Lilly's motion to redefine the interfering subject matter by designating claim 1 of the '529 patent as also corresponding to the count. Lilly timely appealed to this court, and we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

## II. STANDARD OF REVIEW

An agency's interpretation of its own regulations is entitled to substantial deference, and that interpretation will be accepted unless it is plainly erroneous or inconsistent with the regulation. Auer v. Robbins, 519 U.S. 452, 461-62 (1997) (citing Bowles v. Seminole Rock & Sand Co., 325 U.S. 410, 414 (1945)); Am. Express Co. v. United States, 262 F.3d 1376, 1382 (Fed. Cir. 1996).

This court reviews a Board decision pursuant to the permissive rules governing a patent interference proceeding for abuse of discretion. Abrutyn v. Giovanniello, 15 F.3d 1048, 1050-51 (Fed. Cir. 1994) (citing Gerritsen v. Shirai, 979 F.2d 1524, 1527-28 (Fed. Cir. 1992)). An abuse of discretion occurs if the decision (1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact findings; or (4) involves a record that contains no evidence on which the Board could rationally base its decision. Id. This court reviews the legal conclusion of obviousness without deference. In re Gartside, 203 F.3d 1305, 1316 (Fed. Cir. 2000). Anticipation is a question of fact, and this court upholds the decisions of the Board on factual matters if there is substantial evidence in the record to support the Board's findings. In re Hyatt, 211 F.3d 1367, 1371-72 (Fed. Cir. 2000).

### III. DISCUSSION

#### A. 35 U.S.C. § 135(a)

This case presents the question of whether the Director's two-way test for determining whether two parties claim the "same patentable invention" reflects a permissible reading of 37 C.F.R. § 1.601(n), promulgated pursuant to 35 U.S.C. § 135(a), where a species claim to a presumptive senior party allegedly anticipates a genus claim to a presumptive junior party. We also consider whether the Board reasonably has applied the two-way test to dismiss as moot a motion to redefine the interfering subject matter by designating a claim as corresponding to a count.

Pursuant to authority granted by 35 U.S.C. § 135, the Director established the current interference rules to implement the Patent Law Amendments Act of 1984, Pub. L. No. 98-622, §§ 201-02. Patent Interference Proceedings, 49 Fed. Reg. 48,416 (Dec. 12, 1984); 37 C.F.R. § 1.601-1.690 (2003). Section 135 of the United States Code, Title 35, governs patent interference proceedings, which are designed to determine whether two patent applications (or a patent application and an issued patent) are drawn to the "same patentable invention" and, if so, which of the competing parties was first to invent the duplicative subject matter. See Conservolite, Inc. v. Widmayer, 21 F.3d 1098, 1100-01 (Fed. Cir. 1994). The statutory basis for declaring an interference proceeding, 35 U.S.C. § 135(a), reads in pertinent part:

Whenever an application is made for a patent which, in the opinion of the Director, would interfere with any pending application, or with any unexpired patent, an interference may be declared . . . . The Board of Patent Appeals and Interferences shall determine questions of priority of the inventions and may determine questions of patentability.



35 U.S.C. § 135(a) (2000) (emphases added). The plain meaning of this statute demonstrates that Congress has expressly indicated its preference that the declaration of an interference pursuant to § 135 be discretionary. Barton v. Adang, 162 F.3d 1140, 1144 (Fed. Cir. 1998) ("The plain meaning of this statute is clear from the use of the permissive term 'may' that the [Director] has discretion whether to declare an interference."); see also In re Alappat, 33 F.3d 1526, 1531 (Fed. Cir. 1994) (en banc) ("When statutory interpretation is at issue, the plain and unambiguous meaning of a statute prevails in the absence of clearly expressed legislative intent to the contrary."). Section 135(a) states that the Board shall determine questions of priority once an interference proceeding is declared. This authority for the Board to determine questions of priority, however, does not vitiate the Director's discretion to begin or discontinue an interference once declared. See 35 U.S.C. § 135(a). Accordingly, the mandatory language only instructs the Board of its jurisdiction over an active interference. See id.

B. 37 C.F.R. § 1.601(n)

Lilly concedes that 35 U.S.C. § 135(a) permits some discretion, and Lilly also does not raise any general challenge to the Director's reliance on the two-way test to determine whether two parties are claiming the "same patentable invention." Lilly, however, argues that the Director's discretion under 35 U.S.C. § 135(a) is bridled by statutory mandate that requires issuance of only one patent to the first inventor. See 35 U.S.C. § 102(g) (2000). Specifically, where a genus claim to a presumptive junior party is allegedly anticipated by a species claim to a presumptive senior party, Lilly argues that the proper test for whether two claims are the same patentable invention is

a "one-way" test, i.e., the claimed invention of Party A is the same patentable invention as the claimed invention of Party B when the claimed invention of Party A anticipates or renders obvious the claimed invention of Party B, or the claimed invention of Party B anticipates or renders obvious the claimed invention of Party A.

We conclude that the Board properly rejected Lilly's arguments. Under regulations promulgated by the Director, an interference proceeding is declared when two parties are claiming the "same patentable invention." 37 C.F.R. § 1.601(i). According to the regulations, an "interference-in-fact" exists only if both parties to an interference have at least one claim that defines the "same patentable invention." Id. § 1.601(j). The phrase "same patentable invention" is defined as follows:

Invention "A" is the same patentable invention as an invention "B" when invention "A" is the same as (35 U.S.C. [§] 102) or is obvious (35 U.S.C. [§] 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A." Invention "A" is a separate patentable invention with respect to invention "B" when invention "A" is new (35 U.S.C. [§] 102) and non-obvious (35 U.S.C. [§] 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A."

Id. § 1.601(n). The first sentence of § 1.601(n) states that "same patentable invention" means that the invention of one party anticipates or renders obvious the other party's invention. Section 1.601(n) also defines "separate patentable invention" to mean that the invention of one party is new and nonobvious in view of the other party's invention.

The Director, in an amicus brief, interprets § 1.601(n) as requiring a two-way test to determine whether two parties claim the "same patentable invention." The two-way test assures that an interference proceeding will be conducted only when warranted. The Director's approach rejects a wooden requirement under the overinclusive one-way test of declaring an interference proceeding where a species claim allegedly anticipates

a genus claim. If the interference proceeding, however, leads to a conclusion that the genus claim was invented first, it is possible that both the genus and the species are separate patentable inventions. Thus, the Director's two-way test avoids the proliferation of unnecessary, wasteful interference proceedings concluding that both parties are entitled to patents in situations in which the claimed inventions do not define the same patentable invention, but merely overlap in scope. This is the clear application of discretion that is inherent in the authority granted pursuant to 35 U.S.C. § 135(a) of the statute.

Because the two-way test is an interpretation of the Director's own regulations, the Director's interpretation of them is controlling unless "plainly erroneous or inconsistent with the regulation." Auer, 519 U.S. at 461 (citing Seminole, 325 U.S. at 414); see also United States v. Cleveland Indians Baseball Co., 532 U.S. 200, 220 (2001) (giving "substantial judicial deference" to the Internal Revenue Service's reasonable longstanding interpretation of its own regulations); Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994) (noting that the agency's interpretation must be given "controlling weight unless it is 'plainly erroneous or inconsistent with the regulation'" (quoting Seminole, 325 U.S. at 414)); Udall v. Tallman, 380 U.S. 1, 16 (1964) (stating that when "an interpretation of an administrative regulation [is required,] a court must necessarily look to the administrative construction of the regulation if the meaning of the words used is in doubt" (citing Seminole, 325 U.S. at 413-14)); see generally Richard J. Pierce, Jr., Administrative Law Treatise § 6.11 (4th ed. 2002). We have formulated the degree of this deference, under our jurisprudence, variously as "substantial," Am. Express, 262 F.3d at 1382-83, and, in the context of a ruling of the

Board, as "considerable respect," Kubota v. Shibuya, 999 F.2d 517, 520 (Fed. Cir. 1993) (citing Ford Motor Credit Co. v. Milhollin, 444 U.S. 555, 566 (1980)). See also Bayer AG v. Carlsbad Tech., Inc., 298 F.3d 1377, 1381 (Fed. Cir. 2002); Morganroth v. Quigg, 885 F.2d 843, 848 (Fed. Cir. 1989) (stating that the Director's "interpretation of [the regulatory provisions governing abandonment and revival of patent applications] is entitled to considerable deference."). But see Dethmers Mfg. Co. v. Automatic Equip. Mfg. Co., 272 F.3d 1365, 1370 (Fed. Cir. 2001) (subjecting the PTO's interpretation of its own reissue rule to a de novo standard of review), petition for cert. filed, 71 U.S.L.W. 3191 (U.S. Sep. 11, 2002) (No. 02-429).

The deferential standard of Seminole is easily met here.<sup>1</sup> The critical phrase "assuming invention B is the prior art with respect to invention A" comfortably bears the meaning the Director assigns. Because it is not conclusively known which of the two inventions is the prior art and the critical phrase does not require that invention B is the invention of the presumptive senior party, the Director may interpret the phrase to mean that both UW and Lilly may be the assumed "prior art" invention B. Thus, the claimed invention of Party B (UW) is assumed to be prior art vis-à-vis Party A (Lilly) and the claimed invention of Party B (Lilly) is assumed to be prior art vis-à-vis Party A (UW). Thus, under the Director's chosen two-way test, to determine whether two parties are

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<sup>1</sup> To reach Seminole deference, a court must first address the straightforward Chevron question, if presented, of whether a procedural regulation promulgated by the PTO violates the statute. Merck & Co. v. Kessler, 80 F.3d 1543, 1549 (Fed. Cir. 1996) (stating that 35 U.S.C. § 6(a) authorizes the Director to promulgate procedural but not substantive regulations); see also Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842-43 (1984). Because Lilly does not dispute the validity of the regulation, we only address the Seminole question of whether the agency's interpretation is consistent with the regulation.

claiming the "same patentable invention," the claimed invention of Party B (UW) must anticipate or render obvious the claimed invention of Party A (Lilly) and the claimed invention of Party B (Lilly) must anticipate or render obvious the claimed invention of Party A (UW). In the circumstances of this case, where the agency's interpretation of its own regulation is at least as plausible as competing ones, there is little, if any, reason not to defer to the agency's construction.

Besides being textually defensible, the Director's reading of 37 C.F.R. § 1.601(n) comports with the PTO's Notice of Final Rule that accompanied the promulgation of the regulation. 49 Fed. Reg. at 48,433. According to the Notice of Final Rule, the PTO addressed the issue of genus and species claims by stating that genus and species claims define "separate patentable inventions" if the species is "separately patentable from the genus." Id. at 48,433 ("[T]he standard of patentability will not be applied 'on a mutual basis.' Thus, if a species is patentable over a genus, the species is a 'separate patentable' invention from the genus.").

Furthermore, the two-way test for determining whether two parties claim the "same patentable invention" is reasonable and consistent in light of the precedent concerning genus/species inventions. On the one hand, this court has explained, "case law firmly establishes that a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim." Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 971 (Fed. Cir. 2001), cert. denied, 122 S. Ct. 913 (2002). On the other hand, earlier disclosure of a genus does not necessarily prevent patenting a species member of the genus. See, e.g., Bristol-Myers Squibb Co. v. Ben Venue Labs, Inc., 246 F.3d 1368, 1380 (Fed. Cir. 2001).

A primary issue unleashed by application of the two-way test has been whether, under that test, an "interference-in-fact" should exist whenever there exists a theoretical possibility of an interference, or rather only when the parties' claims define the "same patentable invention." This court's case law suggests that the two-way test is underinclusive because it concludes there is no interference-in-fact even if an interference proceeding would have led to the conclusion that the species was invented before the genus. On the other hand, the one-way test is overinclusive because it concludes there is an interference-in-fact even if an interference proceeding would have led to the conclusion that the genus was invented before, and separately patentable from, the species. Section 1.601(n) reasonably can be interpreted to require an election between either a one-way or a two-way test. The Director has reasonably opted for a two-way test to avoid subjecting broad patents for basic inventions to interferences, some of which would have been unnecessary. To read the regulation, as Lilly and our colleague in dissent urge, to require the continuance of an interference proceeding where a genus claim to a presumptive junior party is allegedly anticipated by a species claim to a presumptive senior party, is a plausible alternative reading, but a reading which in the Director's discretion he has chosen not to accept.

While Lilly's objections would perhaps support an alternative one-way test where a species claim to a presumptive senior party allegedly anticipates a genus claim to a presumptive junior party, we cannot conclude that they compel it. The Director's view that a presumptive senior party with a species claim and a presumptive junior party with a genus claim are not so differently situated with regard to determining a separate patentable invention as to require revision of the Director's long-standing two-way test

simply cannot be said to be unreasonable. Accordingly, we hold that the Director's interpretation of 37 C.F.R. § 1.601(n) as establishing a two-way test for determining whether two parties are claiming the "same patentable invention" is neither plainly erroneous nor inconsistent with the language of the regulation.

C. Motion to Designate Claim 1 of the '529 Patent as Corresponding to the Count

One issue remains unresolved: Lilly asks this court to vacate the Board's dismissal of Lilly's motion under 37 C.F.R. § 1.633(c)(3) to redefine the interfering subject matter by designating claim 1 of the '529 patent as corresponding to the count, because Lilly believes the Board manifestly erred by not definitively construing the claim before applying the two-way test. While in many cases this proposition is correct, for the reasons given below, it is possible under the particular circumstances of this case for the Board to dismiss the motion to designate claim 1 of the '529 patent as corresponding to the count even if the claim is not definitively construed.

"A count defines the interfering subject matter between two or more applications or between one or more applications and one or more patents." 37 C.F.R. § 1.601(f). Typically, the PTO determines which claims correspond to the count in order to determine the subject matter of the interference. Id. ("Any claim of an application or patent that is designated to correspond to a count is a claim involved in the interference . . . ."); id. § 1.603. In determining whether it is proper to designate an application or patent claim to correspond to a count, the pertinent inquiry is whether that "claim defines the same patentable invention as another claim whose designation as corresponding to the count the moving party does not dispute." Id. § 1.637(c)(3)(ii). In that regard, what constitutes the "same patentable invention" is defined by 37 C.F.R. §

1.601(n), which was formulated to determine the extent of interfering subject matter as between applications (or a patent application and an issued patent) of potentially conflicting parties. See In re Van Geuns, 988 F.2d 1181, 1185 (Fed. Cir. 1993). Accordingly, the two-way test promulgated pursuant to 37 C.F.R. § 1.601(n), as discussed above, Part III.B, supra, is applied to determine whether a claim is properly designated to correspond to the count.

That the Board failed definitively to construe claim 1 of the '529 patent is plain enough. To the extent that any procedural error occurred, however, we conclude that the Board did not commit reversible error in this case because the Board applying the two-way test found that, whether construed broadly or narrowly, claim 1 of the '529 patent does not define the same patentable invention as the corresponding claims 1-82 and 84-90 of the '663 reissue application, whose correspondence to the count Lilly does not dispute. The Director's two-way test is usefully illustrated by reference to this case.

First, with respect to the species claim construction of claim 1 of the '529 patent proposed by Lilly, the Board found no interference-in-fact because the specific cDNA sequence of claim 1 of the '529 patent does not teach or suggest the cDNA sequences claimed in the corresponding claims of the '663 reissue application. Because the cDNA sequences claimed in the corresponding claims of the '663 reissue application are not anticipated by and not obvious over a narrowly construed claim 1 of the '529 patent (assuming the '529 patent is the prior art), the cDNA sequences claimed in the '663 reissue application do not define the same patentable invention. Thus, under the species claim construction as proposed by Lilly, the Board found that Lilly failed to carry



its burden to show that claim 1 of the '529 patent should be designated as corresponding to the count.

Similarly, with respect to the genus claim construction of claim 1 of the '529 patent proposed by Lilly, the Board found no interference-in-fact because the evidence presented failed to teach or suggest the selection of the cDNA sequences claimed in the corresponding claims of the '663 reissue application from among the vast number of cDNA sequences potentially encompassed by a broadly construed claim 1 of the '529 patent. Because the cDNA sequences claimed in the corresponding claims of the '663 reissue application are not anticipated by and not obvious over a broadly construed claim 1 of the '529 patent (assuming the '529 patent is the prior art), the cDNA sequences claimed in the '663 reissue application do not define the same patentable invention. Thus, under the genus claim construction as proposed by Lilly, the Board also found that Lilly failed to carry its burden to show that claim 1 of the '529 patent should be designated as corresponding to the count.

The Board therefore tested both of Lilly's proposed claim constructions for interfering subject matter. Because neither construction yielded the same patentable invention as any of the corresponding claims of the '663 reissue application, however, it was unnecessary for the Board to adopt either one of the two claim constructions proffered by Lilly as definitive. Accordingly, we hold that the Board did not commit reversible error when it dismissed as moot Lilly's motion to redefine the interfering subject matter by designating claim 1 of the '529 patent as corresponding to the count, because there was no interference-in-fact based on either of the two claim constructions proposed by Lilly of claim 1 of the '529 patent. Based on this procedure,

namely accepting both constructions proposed by Lilly of claim 1 of the '529 patent and finding that upon either claim construction no interference-in-fact need be declared, there was no need by the Board to definitively construe the claim.

#### IV. CONCLUSION

The issue is not without its difficulties whichever way we turn. Though not the sole permissible one, the Director's interpretation of 37 C.F.R. § 1.601(n) as establishing a two-way test for determining whether two parties claim the same patentable invention is neither plainly erroneous nor inconsistent with the regulation. The discretionary authority granted to the Director in establishing interferences must be given considerable respect and, when it is neither plainly erroneous nor inconsistent with the promulgated regulation, cannot be second-guessed by this court and must be affirmed. We also hold that the Board committed no reversible error in applying the two-way test to determine that the '529 patent and the corresponding claims of the '663 reissue application do not define the same patentable invention. The judgment of the Board is

AFFIRMED.

# United States Court of Appeals for the Federal Circuit

02-1610  
(Interference No. 104,733)

ELI LILLY & CO.

Appellant,

v.

BOARD OF REGENTS OF THE UNIVERSITY OF WASHINGTON,

Appellee.

LOURIE, Circuit Judge, dissenting.

I agree that the Director has discretion whether or not to declare an interference. The statute, 35 U.S.C. § 135, expressly provides that "Whenever an application is made for a patent which, in the opinion of the Director, would interfere with any pending application, or with any unexpired patent, an interference may be declared." (emphases added). However, that discretion is not unlimited. It is cabined by the requirement that it not be exercised contrary to the statute under which the Director operates the PTO, and, of particular importance here, the Director must exercise his discretion in a manner that complies with the Patent Office rules of practice.

The Board of Patent Appeals and Interferences here declined to declare an interference between Lilly's reissue application and the University of Washington's patent on the ground that a two-way test applies for determining whether the claims presented by the parties create an interference-in-fact, and, under that test, the parties do not claim the same invention. In so holding, the Board relied on its own decision in Winter v. Fujita, 53 USPQ2d 1234 (Bd. Pat. App. & Int. 1999), and its strained

interpretation of 37 C.F.R. § 1.601(n) ("Rule 601(n)") set forth therein. The Board also either failed to consider or chose to ignore the fact that, on the record, Lilly is senior to UW.

I believe the Board's action constitutes an abuse of discretion because the language of Rule 601(n) plainly describes a one-way test and does not support a two-way test. While Winter does hold that a two-way test is appropriate, its conclusion, not binding on us, is unsupported by any reasoning. UW and the majority opinion argue that the PTO's comments in promulgating its interference rules should be considered in our interpretation of the rules, but, when they are contrary to their plain meaning, such comments cannot alter the meaning of the rules.

The Board found that there was no interference-in-fact between claims 1-82 and 84-90 of Lilly's U.S. Reissue application 09/185,663, on the one hand, and claims 1 and 3 of UW's issued '529 patent, on the other. Rule 601(j) (i.e., 37 C.F.R. § 1.601(j)) defines the existence of an interference-in-fact in terms of whether or not the parties claim the "same patentable invention," a term that is defined in Rule 601(n). Rule 601(n) reads as follows:

Invention "A" is the *same patentable invention* as an invention "B" when invention "A" is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A." Invention "A" is a *separate patentable invention* with respect to invention "B" when invention "A" is new (35 U.S.C. 102) and non-obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A."

(second emphasis added).

In each case, a one-way test is set forth: whether invention A is the same as or is obvious with respect to invention B, assuming B is prior art with respect to A. The rule

does not require that B be the same as or obvious with respect to A, or assume that A is prior art with respect to B. Thus, the rule provides a one-way test, not a two-way test, as the Board erroneously held.

In the case before us, the parties agree that UW's claim 3 is patentably distinct from Lilly's claims 1-82 and 84-90, even though the sequences they claim differ from each other only in two codons out of 419 and yield the same peptide product. Hence, they do not claim the same invention and there is no interference-in-fact with respect to those claims.

As for UW's claim 1, the Board did not construe that claim to determine whether it is generic or directed to a species. Although Lilly has not asked us to construe claim 1 as a generic claim, it asserts that it was error for the Board not to construe the claim at all. Claim construction is a matter of law and construction of claim 1 is necessary to the resolution of this appeal. Claim 1 is directed to a nucleic acid plasmid or vector comprising cDNA coding for a specified 419 amino acid sequence shown in Figure 3 of the patent. Given the degeneracy of the genetic code, the parties agree, or at least do not contest, that the indicated 419 amino acid sequence can be coded for by more than  $10^{23}$  different cDNA sequences. Thus, it is clear that claim 1 covers all of those cDNA sequences, and must therefore be construed as generic.

Applying the one-way test clearly set forth by Rule 601(n), UW's generic claim 1 must be held to be the same patentable invention, not because a genus and a species are the same, but because Rule 601(n) refers to 35 U.S.C. § 102 after its reference to "same invention," and thereby indicates that the phrase "same patentable invention" encompasses the concept of "is anticipated by." Lilly, on the present record, would be

the senior party were an interference to be declared. Clearly, the species in Lilly's prior filed claims anticipates UW's later-filed generic claim. If an interference were to be declared, UW might antedate Lilly's claim, in which case UW's generic claim would remain in force. In that case, however, Lilly's species claim would also remain, because the Board already found the species to be a separate patentable invention with respect to the prior genus. The interference will seem to have been conducted in vain, but the issues will have been settled in accordance with the statutory procedure for resolving a possible conflict of priority between an application (albeit a reissue application) and a patent. If UW does not antedate Lilly's species, then UW's generic claim will be invalid under 35 U.S.C. § 102(g), and the matter will have been settled by the optimal tribunal.

The majority and the Director urge that upholding the Board's decision would avoid unnecessary interferences, which it is said are a burden on the Patent Office. The answer to that assertion is that it is the job of the Office, which has the expertise to evaluate contending claims for patent, to determine which of those claims have priority and should issue as patents. It is clearly more efficient for even an overburdened Patent Office to make determinations in the arcane world of interferences than for the overburdened courts to do so.

In the present case, affirmance may well lead to a prolonged action in a district court unaccustomed to evaluating interference issues involving cDNA sequences, whereas reversal would result in the more experienced Patent Office determining the respective rights of the parties. Such a determination would likely not be overturned by the courts, see In re Gartside, 203 F.3d 1305, 1316, 53 USPQ2d 1769, 1776 (Fed. Cir.

2000), thereby leaving the first and most important determination of a complex factual matter in the tribunal best able to carry it out.

In summary, the Board abused its discretion by interpreting Rule 601(n) to require a two-way test for determining when separate patentable inventions are involved and by failing to consider the effective filing dates of the respective parties. I would therefore reverse the Board's decision finding no interference-in-fact.

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IS A TRUE AND CORRECT COPY  
OF THE ORIGINAL ON FILE.

UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT

By: Christa Thomas Date: 10/22/13